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No. 2024-1285

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission
in Investigation No. 337-TA-1276

NON-CONFIDENTIAL JOINT APPENDIX

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CERTIFICATE OF SERVICE

CONFIDENTIAL MATERIAL OMITTED

The material omitted from Appx9; Appx36; Appx41-44; Appx46-48; Appx108; Appx119; Appx121-122; Appx150-151; Appx153-154; Appx156-158; Appx187-190; Appx192-194; Appx196; Appx198; Appx218; Appx220-222; Appx265-276; Appx373; Appx13067-13069; Appx21846; Appx22790; Appx22954; Appx22956-22958; Appx22985; Appx22990; Appx23139; Appx23166; Appx23171-23174; Appx23238; Appx23249; Appx23251-23252; Appx23280-23281; Appx23283-23284; Appx23286-23288; Appx23317-23320; Appx23322-Appx23323; Appx23326; Appx23328; Appx23348; Appx23350-23352; Appx23395-23406; Appx23656; Appx23658; Appx23681-23682; 23688; Appx23791; Appx24147-24148; Appx40795-40798; Appx40996-40999; Appx41019-41026; Appx41029-41030; Appx41058-41062; Appx41077-41080; Appx41094-41097; Appx41108-41110; Appx51900-51924; Appx52602-52606; Appx52609; Appx52642-52645; Appx52791-52795; Appx52822-52824; Appx52911-52912; Appx52939-52941; Appx52980-52982; Appx53016-53019; Appx60425-60431; Appx60432-60434; Appx70322-70355; Appx70774; Appx70781-70783; and Appx70841-70876 contains Apple's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx4579 and Appx53459-53461 contains competitively sensitive information regarding confidential agreements; the material omitted from Appx23439; Appx23441-23446; Appx23448; Appx23450-23453; Appx23455-23458; Appx23462; Appx23617; Appx23621; Appx23659-23665; Appx25251; Appx40483; Appx40582-40584; Appx40600-40601; Appx40605; Appx40652-40655; Appx40658-40662; Appx53491; Appx53492; Appx53497; Appx53499; Appx53503; Appx53506; Appx65064-65075; Appx65075; Appx65104-65105; Appx65315; Appx65321-65232; and Appx71223-71244 contains Masimo's confidential competitively sensitive financial information subject to the Administrative Protective Order; the material omitted from Appx311-316; Appx23667-23674; Appx40579-40581; Appx40585-40599; Appx40602-40604; Appx40610-40614; and Appx40631-40633 contains Masimo's confidential competitively sensitive financial and manufacturing information subject to the Administrative Protective Order; the material omitted from Appx473-474; Appx62; and Appx23176-23178 contains Masimo's confidential competitively sensitive manufacturing information subject to the Administrative Protective Order; the material omitted from Appx13047; Appx14129-14140; Appx205-206; Appx211; Appx21848; Appx22282-22286; Appx23197; Appx23204; Appx23335-23336; Appx23341; Appx23408-23416; Appx23434-23436; Appx23454; Appx23642; Appx23644-23645; Appx23647-23649; Appx23685-23687; Appx23693-23697; Appx23704; Appx25253-25260; Appx278-286; Appx2809-

2852; Appx2923-2937; Appx304-306; Appx309; Appx3708; Appx3710-3711; Appx3718; Appx3722; Appx3725; Appx3727; Appx3732; Appx3733; Appx3735; Appx40229-40232; Appx40346-40371; Appx40407-40422; Appx40431-40434; Appx40438-40442; Appx40486-40494; Appx40495-40506; Appx40512-40521; Appx40525-40528; Appx40547-40555; Appx40560-40574; Appx40803-40822; Appx41217-41221; Appx41350-41356; Appx53070-53095; Appx53107-53151; Appx53222-53234; Appx53236-53252; Appx53256-53361; Appx53362-53365; Appx53813-53838; Appx53927-53941; Appx54064-54226; Appx54227-54266; Appx55229-55354; Appx55359-55376; Appx55386-55399; Appx57317-57324; Appx57394--57409; Appx57410-57412; Appx57615-57618; Appx60136-60153; Appx60184-60212; Appx65014-65019; Appx65022-65025; Appx65028-65037; Appx65040-65074; Appx65207; Appx65224; Appx65267-65268; Appx67; Appx6701-6703; Appx6705; Appx6732-6736; Appx6852-6854; Appx6937-6950; Appx70475; Appx70484-70491; Appx70504-70513; Appx70518-70559; Appx70610-70613; Appx70615-70617; Appx70619-70628; Appx70833-70835; Appx70948-70950; Appx70955-70956; and Appx74 contains Masimo's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx23707-23709; Appx318; Appx320-328; Appx40634; and Appx70592-70594 contains Masimo's confidential competitively sensitive product and financial information subject to the Administrative Protective Order; the material omitted from Appx176; Appx179; Appx22788-22789; and Appx22791 contains Masimo's confidential information detailing non-public patent prosecution subject to the Administrative Protective Order; the material omitted from Appx404-405; Appx457; Appx460-461; Appx464; Appx24103-24104; Appx25387; and Appx25389 contains Apple's confidential competitively sensitive financial and sales information subject to the Administrative Protective Order; the material omitted from Appx52602-52608 contains confidential competitively sensitive product of a third party.

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【0010】

本発明は、上述した問題点を解決するためになされたものであり、どちらの手の指を測定部位として測定する場合であっても、安定した装着状態で測定結果を視認することのできる生体情報測定装置を提供することを目的とする。

【課題を解決するための手段】

【0011】

請求項1に記載の発明は、特定の指を測定部位として所定の生体情報を測定する測定部と、前記測定部により測定される生体情報に由来する生体信号に基づき、生体情報に係るデータを導出する導出部とを内蔵する筐体構造を備え、前記測定部に装着される生体情報測定装置であって、前記筐体を貫通する貫通孔と、前記筐体の外壁面に設けられ、前記導出部によって導出された生体情報に係るデータを表示する表示面が前記貫通孔に略沿って形成された表示部とを備え、前記測定部は、前記貫通孔に挿入された指を測定部位として所定の生体情報を測定することを特徴とするものである。

【0012】

この発明によれば、前記筐体を貫通する貫通孔と、前記筐体の外壁面に設けられ、前記導出部によって導出された生体情報に係るデータを表示する表示面が前記貫通孔に略沿って形成された表示部とを備えたので、一方の手の指を測定部位とするときは、前記貫通孔の一方の開口端から該指を挿入し、他方の手の指を測定部位とするときは、前記貫通孔の他方の開口端から該指を挿入するという装着が可能となり、どちらの手の指を測定部位として測定する場合であっても、表示部を被験者の顔に正対させた状態で測定を行うことが可能となる。

【0013】

前記筐体の構造の一例として、例えば請求項2に記載の発明のように、前記筐体は、本体部と、前記本体部の一侧部に設置されたカバーとを有してなり、前記貫通孔は、前記本体部と前記カバーとが対向した状態で形成される形態が想定される。

【0014】

請求項3に記載の発明は、請求項2に記載の生体情報測定装置において、前記本体部と前記カバーとの間には、前記貫通孔と略平行な支持軸と、該支持軸と嵌合する嵌合孔とを有する嵌合構造が構成されており、前記嵌合構造は、前記カバーを前記支持軸を中心として回動可能とすることを特徴とするものである。

【0015】

この発明によれば、前記本体部と前記カバーとの間に、前記貫通孔と略平行な支持軸と、該支持軸と嵌合する嵌合孔とを有する嵌合構造を構成するとともに、前記カバーを前記支持軸を中心として回動可能に構成したので、前記カバーの回動だけで測定指への生体情報測定装置の着脱が行われる。

【0016】

請求項4に記載の発明は、請求項2または3に記載の生体情報測定装置において、前記本体部と前記カバーとの間には、前記貫通孔と略平行な支持軸と、該支持軸と嵌合する嵌合孔とを有する嵌合構造が構成されており、前記嵌合孔は、一方向に長尺の形状を有し、前記嵌合構造は、前記支持軸が前記嵌合孔内を相対移動することにより、前記カバーを前記本体部に対し対接離反方向に平行移動可能とすることを特徴とするものである。

【0017】

この発明によれば、前記本体部と前記カバーとの間に、前記貫通孔と略平行な支持軸と、該支持軸と嵌合する嵌合孔とを有する嵌合構造を構成するとともに、前記支持軸が一方向に長尺の形状を有する嵌合孔内を相対移動することにより、前記カバーを前記本体部に対し対接離反方向に平行移動可能に構成したので、測定指が前記カバーと前記本体部とにより該測定指に対して互いに反対側の位置で挟み込まれる。

【0018】

請求項5に記載の発明は、請求項1ないし4のいずれかに記載の生体情報測定装置において、前記貫通孔は、該貫通孔に正規の姿勢で指が挿入された状態を想定したとき、該指

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の腹の部分が反るように、該貫通孔の長手方向に平行な面による切断面が凹形状に形成されていることを特徴とするものである。

【0019】

この発明によれば、前記貫通孔は、該貫通孔に正規の姿勢で指が挿入された状態を想定したとき、該指の腹の部分が反るように、該貫通孔の長手方向に平行な面による切断面が凹形状に形成されているので、指の構造と前記貫通孔の形状との関係から貫通孔に対する指の位置決めが行われる。

【0020】

請求項6に記載の発明は、請求項1ないし5のいずれかに記載の生体情報測定装置において、前記筐体は、略直方形状を有しており、前記貫通孔は、前記筐体における略平行な2の外壁面に交差する面に略沿って形成されており、前記表示部は、前記2の外壁面のうちいずれか一方の外壁面に設置されていることを特徴とするものである。

【0021】

この発明によれば、前記筐体が略直方形状を有し、前記表示部が前記2の外壁面のうちいずれか一方の外壁面にしか設置されていない生体情報測定装置であっても、前記貫通孔を、前記筐体における略平行な2の外壁面に交差する面に略沿って形成することにより、どちらの手の指を測定部位として測定する場合でも、表示部を被験者の顔に正対させた状態で測定を行うことが可能となる。

【発明の効果】

【0022】

請求項1, 2, 6に記載の発明によれば、どちらの手の指を測定部位として測定する場合であっても、表示部を被験者の顔に正対させた状態で測定を行うことが可能となるため、安定した装着状態で測定を行うことができる。また、どちらの手の指を測定部位としても容易に測定結果を視認することができるため、生体情報測定装置の利便性を向上することができる。

【0023】

請求項3に記載の発明によれば、前記カバーの回動だけで測定指への生体情報測定装置の着脱が行われるようにしたので、生体情報測定装置の指への着脱を容易に行うことができ、生体情報測定装置の利便性を向上することができる。

【0024】

請求項4に記載の発明によれば、前記カバーと前記本体部とにより測定指に対して互いに反対側の位置で該測定指が挟み込まれるようにしたので、測定指を前記カバーと前記本体部とで確実に挟み込むことができ、安定した装着状態で測定を行うことができる。

【0025】

請求項5に記載の発明によれば、指の構造と前記貫通孔の形状との関係から貫通孔に対する指の位置決めが行われるようにしたので、貫通孔に対する指の位置決めを行うための部材を別途設けることなく該位置決めを行うことができ、前記位置決めのための部品の点数増加を防止することができる。

【発明を実施するための最良の形態】

【0026】

以下、本発明に係る生体情報測定装置の一実施形態であるパルスオキシメータについて説明する。図1は、パルスオキシメータの外観を示す斜視図であり、図2は、パルスオキシメータの一断面図、図3は、図2におけるA-A線からみた矢視断面図である。なお、図1における矢印Bが示す方向を左右方向、矢印cが示す方向を表裏方向というものとする。

【0027】

図1～図3に示すように、パルスオキシメータ1は、携帯性を有する直方形状の装置であり、本体部2と、該本体部2の上部に配置されたカバー3とを有して構成されている。

【0028】

本体部2は、所要の厚みを有する略直方平板形状を有し、平板状を呈している一側面に

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、測定結果を表示するための表示部4が備えられている。なお、この一側面と該面と反対側の平板状を呈する面とは、前記2の外壁面の一例である。

【0029】

また、前記一側面に設けられた表示部4の一側方には、右手の指にパルスオキシメータ1が装着された場合に、該右手の親指で把持される把持部2aが設けられており、前記表示部4の他側方には、左手の指にパルスオキシメータ1が装着された場合に、該左手の親指で把持される把持部2bが設けられている。なお、把持部2a、2bには、親指の滑り止めのため、粒状に形成された複数の突起又は凹部2a-1、2b-1が形成されている。

【0030】

本体部2は、その上面に左右方向に延びる凹部2cを有しており、該凹部2cを構成するハウジングの左右方向における略中央位置には、穴部2dが形成されている。また、この穴部2dを塞ぐように、前記ハウジングの内壁面所定位置には後述する受光部5が取り付けられている。

【0031】

また、本体部2の裏面側に形成された延設部2eには、前記穴部2dの上方で該穴部2dと対面する位置まで延びる形状を有するアーム6が設置されており、該アーム6の先端部の下面には、前記受光部5とが対向するように後述の発光部7が取り付けられている。

【0032】

本体部2の上面における裏面側端部には、左右方向に延びる支持軸8が構成されている一方、カバー3は、この支持軸8に外嵌する嵌合部3cが形成されており、該嵌合部3cと前記支持軸8との嵌合により前記カバー3が、図1に示すように前記凹部2cが外部に露出する開放位置と、前記凹部2cが該カバー3により覆われる閉鎖位置との間で矢印a方向に回転自在に軸支されている。また、カバー3は、図略の巻きバネ等の付勢部材により前記開放位置から閉鎖位置に向かう方向に付勢されている。

【0033】

カバー3の左右各端部には、それぞれ凹形状の切欠き部3a、3bが形成されており、パルスオキシメータ1には、カバー3が前記閉鎖位置に位置するとき、前記切り欠き部3a、3bと本体部2の上面に形成された凹部2cとで、指が嵌め込まれる貫通孔9が形成される。

【0034】

指に当該パルスオキシメータ1を装着するときには、カバー3を前記付勢力に抗して前記開放位置まで回転させ、その指を前記本体部2の上面の凹部2cに載置した状態でカバー3を付勢力によって閉鎖位置に位置させる。これにより、カバー3の前記切欠き部3a、3bを構成するハウジングの端部や、この端部に対向する前記本体部2の端部は該指を挟持する。なお、カバー3を前記付勢力に抗して前記開放位置まで回転させることで、指から当該パルスオキシメータ1を取り外すことができる。

【0035】

このように、パルスオキシメータ1は、左右方向に貫通する前記貫通孔9が形成されているため、表示部4を被験者の顔（眼）に正対させた状態で左右いずれの手の指にも装着可能となる。

【0036】

なお、本体部2の内部には、例えばバッテリーや乾電池等の電力供給部（図示せず）を有し、前記表示部4や、本体部2に搭載される各種の回路及び後述する測定部10はこの電力供給部から電力供給を受けて駆動する。

【0037】

図4は、パルスオキシメータ1の電気的な構成を示すブロック図である。図4に示すように、パルスオキシメータ1は、測定部10、表示部4、電流電圧変換部（以下、I/V変換部という）11、アナログデジタル変換部（以下、A/D変換部）12及び制御部13を備える。

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【0038】

測定部10、表示部4は、図1に示す測定部10、表示部4に相当するものである。表示部4は、例えばLCD(Liquid Crystal Display)、7セグメントLED(Light Emitting Diode)や有機ホトミネセンス表示装置、あるいはプラズマ等の表示装置からなり、後述の制御部13で算出されたデータ等を表示する。

【0039】

I/V変換部11は、例えば1/40(秒)の周期で受光部5から出力される電流信号を電圧信号に変換し、この電圧信号を光電脈波信号としてA/D変換部12に出力するものである。A/D変換部12は、I/V変換部11から出力されたアナログの光電脈波信号をデジタルの光電脈波信号に変換し、このデジタルの光電脈波信号を制御部13に出力するものである。

【0040】

制御部13は、マイクロプロセッサやDSP(Digital Signal Processor)などを備えて構成されており、図略の記憶部に格納されているデータやプログラムに従って、入力された光電脈波信号から動脈血中の酸素飽和度を演算するものである。制御部13は、測定制御部14と、バンドパスフィルタ部(以下、「BPF部」と略記する)15と、酸素飽和度演算部16と、表示制御部17とを有する。

【0041】

測定制御部14は、測定部10の発光部7及び受光部5の動作を制御するものであり、本実施形態では、波長λ1の赤色光R及び波長λ2の赤外光IRをそれぞれ例えば1/40(秒)の周期で発光部7から交互に射出させる。

【0042】

BPF部15は、デジタルフィルタで構成されており、A/D変換部12によりA/D変換された光電脈波信号をフィルタリングするものである。なお、BPF部15は、デジタルローパスフィルタ及びデジタルハイパスフィルタから構成してもよいし、FIR(Finite Impulse Response)フィルタで構成してもよい。

【0043】

酸素飽和度演算部16は、BPF部15によりフィルタリングされた光電脈波信号に基づいて、測定した各時点での酸素飽和度(以下、この酸素飽和度を瞬間酸素飽和度という)及び脈拍数を算出する。

【0044】

ここで、酸素飽和度演算部16による光を用いた血中酸素飽和度を導出する原理について説明する。

【0045】

酸素は、血中のヘモグロビン(Hb)によって生体の各細胞に運搬され、ヘモグロビンは、肺で酸素と結合して酸化ヘモグロビン(HbO₂)となり、生体の細胞で酸素が消費されるとヘモグロビンに戻る。酸素飽和度SpO₂は、血中の酸化ヘモグロビンの割合をいい、ヘモグロビン濃度をCHb、酸化ヘモグロビン濃度をCHbO₂と表すと、下記式(1)で表される。

【0046】

【数1】

$$SpO_2 = \frac{CHbO_2}{CHb + CHbO_2} \quad \dots(1)$$

【0047】

一方、ヘモグロビンの吸光度及び酸化ヘモグロビンの吸光度は、波長依存性を有しており、各吸光係数α(λ)は、図5に示すような吸光特性を有する。なお、図5の横軸は光の波長であり、単位はnm、縦軸は、吸光係数であり、単位は10⁻⁹cm²/moleである。

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【0048】

図5に示すように、ヘモグロビン及び酸化ヘモグロビンは、吸光特性が異なる。ヘモグロビンは、赤色領域の波長 λ_1 の赤色光Rに対して酸化ヘモグロビンよりも光を多く吸収するが、赤外線領域の波長 λ_2 を超える赤外光IRに対しては酸化ヘモグロビンよりも光の吸収が少ない。すなわち、例えば赤外光IRの波長を酸化ヘモグロビンとヘモグロビンとの吸光係数差が最も大きい660nmとし、赤外光IRの波長を酸化ヘモグロビンとヘモグロビンとの吸光係数が等しい815nmとすると、酸化ヘモグロビンとヘモグロビンとの比率が変化しても赤外光IRの透過光量は変化しないこととなる。一方、赤色光Rの透過光量はヘモグロビンが多いと小さくなり、酸化ヘモグロビンが多いと大きくなる。つまり、透過光量の比をとれば酸素飽和度を求めることができる。

【0049】

パルスオキシメータ1は、このようなヘモグロビンと酸化ヘモグロビンとの赤色光Rと赤外光IRとに対する吸光特性の違いを利用して血中酸素飽和度を求めるとともに、ヘモグロビンと酸化ヘモグロビンとの赤色光Rと赤外光IRとに対する吸光特性の違いを利用して脈拍数も求める。

【0050】

生体に光を照射すると、光の一部は吸収され、残りは透過する。生体は、動脈血層と、静脈血層と、動脈血層及び静脈血層以外の組織とで構成されている。生体における光の吸収は、図6(a)に示すように、動脈血層及び静脈血層以外の組織による吸収、静脈血層による吸収及び動脈血層による吸収より成る。動脈血層及び静脈血層以外の組織と静脈血層とは経時的に変化しないため、この部分での光の吸収は略一定である。

【0051】

一方、動脈血層は心拍動によって血管の径が変化するため、動脈血層による光の吸収は、図6(b)に示すように脈拍による経時的に変動する。つまり、透過光強度の変化分は、動脈血のみの情報によるものであって、動脈血層及び静脈血層以外の組織と静脈血層とによる影響はほとんど含まれないと考えられる。図6(b)において、横軸は時間、縦軸は透過光強度を示す。

【0052】

赤色光R及び赤外光IRの光量変化を比較する場合、入射光量の差をキャンセルする必要がある。図7は、生体に入射する入射光と透過光との関係を模式的に示す図である。

【0053】

図7(a)に示すように、生体への入射光量IOを赤色光Rと赤外光IRとで同一にすることは実質的に困難であり、仮に同一にしても組織や静脈血による吸光率は赤色光Rと赤外光IRとで異なるため、動脈血層による透過光強度の変化分のみを比較することはできない。

【0054】

ここで、図7(b)に示すように、動脈が一番細い場合(透過光量が最も大きくなる場合)の透過光量をIとし、動脈が最も太い場合(透過光量が最も小さくなる場合)の透過光量を $(I - \Delta I)$ とする。図7(c)に示すように、厚さ ΔD の動脈血に光量Iの光を照射したとき、透過光量 $(I - \Delta I)$ の透過光が得られると考えられる。

【0055】

そして、図8に示すように、赤色光Rの透過光量 I_R と赤外光IRの透過光量 I_{IR} とが一致するように正規化する $(I_{IR} \cdot = I_R)$ ことにより、動脈血による光量変化の比 $(\Delta I_R / I_R) / (\Delta I_{IR} / I_{IR})$ を算出し、酸素飽和度を算出する。

【0056】

入射光と反射光との関係は、ランバート・ビアの法則により、下記式(2)で表すことができる。

【0057】

【数2】

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$$\log\left(\frac{I}{I-\Delta I}\right)=EC_{\Delta}D \quad \cdots(2)$$

【0058】

なお、Eは吸光物の吸光係数、Cは吸光物の濃度を表す。

【0059】

赤色光R及び赤外光IRの各波長を前記式(2)に代入し、各辺の比をとることにより、下記式(3)式を得ることができる。

【0060】

【数3】

$$\frac{\log\{I_R/(I_R-\Delta I_R)\}}{\log\{I_{IR}/(I_{IR}-\Delta I_{IR})\}}=\frac{E_R C_{\Delta} D}{E_{IR} C_{\Delta} D}=\frac{E_R}{E_{IR}} \quad \cdots(3)$$

【0061】

なお、 I_R は、赤色光Rの透過光量、 I_{IR} は、赤外光IRの透過光量、 E_R は、赤色光Rの吸光係数、 E_{IR} は、赤外光IRの吸光係数を表す。

【0062】

図9は、例えば赤色光R及び赤外光IRの各波長を、それぞれ660nm及び815nmとしたときにおける、吸光係数の比(E_R/E_{IR})と酸素飽和度 SpO_2 との関係を示すグラフである。図9に示すように、酸素飽和度 SpO_2 は、吸光係数の比(E_R/E_{IR})の低下に比例して増大していく。

【0063】

図4に戻り、表示制御部17は、前記のようにして酸素飽和度演算部16により算出された測定結果(酸素飽和度及び脈拍数)を表示部4に表示させるものである。

【0064】

図10は、パルスオキシメータ1における測定結果の表示処理を示すフローチャートである。

【0065】

図10に示すように、制御部13は、測定開始の指示がなされると(ステップ#1でYES)、赤外LEDを発光させるとともに受光部5に受光動作を行わせ、該受光部5から得られる受光信号を用いて、 SpO_2 の導出処理を行う測定動作を実行する(ステップ#2)。そして、制御部13は、測定結果を表示部4に表示させる(ステップ#3)。

【0066】

以上のように、パルスオキシメータ1に左右方向に貫通する貫通孔9が形成されるように構成したので、図11(a)に示すように、表示部4を被験者の顔(眼)に正対させた状態で、左手の指に当該パルスオキシメータ1を装着することができるとともに、図11(b)に示すように、表示部4を被験者の顔(眼)に正対させた状態で、右手の指にも当該パルスオキシメータ1を装着することができる。

【0067】

したがって、従来のように装着可能な手が実質的に制限されることがなく、どちらの手の指に装着する場合であっても、安定した装着状態で被験者は容易に測定結果を視認することができる。

【0068】

また、被験者の利き手が左右どちらの手であってもパルスオキシメータ1を指に装着した状態で該パルスオキシメータ1を確実に保持することができる。また、一方の手に怪我を負っていて、その手の指にはパルスオキシメータ100を装着できない場合に、他方の手の指にパルスオキシメータを装着すると、前記表示部104が被験者の顔と反対側(裏

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側)に位置することとなるという状態が発生することもない。

【0069】

その結果、パルスオキシメータ1の不安定な装着状態に起因する測定精度の低下を回避することができるとともに、パルスオキシメータ1の利便性を向上することができる。

【0070】

また、前記貫通孔9を、上面に左右方向(矢印B方向)に延びる凹部2cを有する本体部2と、左右両端部にそれぞれ形成された凹形状の切欠き部3a、3bを有するカバー3とで構成し、単にカバー3を本体部2に対して開閉(回動)するだけでパルスオキシメータ1を指に装着できるようにしたので、パルスオキシメータ1の指への装着が容易となる。

【0071】

本件は、前記実施形態に加えて、あるいは前記実施形態に代えて次の形態[1]～[6]に説明する変形形態も含むものである。

【0072】

[1] 前記第1の実施形態においては、前記アーム6の先端部の下面に発光部7を設置したが、図12(貫通孔に略直交する平面による断面)の矢印Xで示すように、アーム6を有していないパルスオキシメータについては、カバー3を構成するハウジングを延設し、該ハウジングのうち前記受光部5に対向する位置に設置するようにしてもよい。

【0073】

また、酸素飽和度の測定を行うためのものとして、前記第1の実施形態のように、対向配置された発光部7と受光部5との間に指が挿入され、透過光に基づいて酸素飽和度の測定を行う光透過型のパルスオキシメータではなく、図13(貫通孔に略直交する平面による断面)に示すように、発光部7と受光部5とが例えば本体部2の所定位置に隣接して配置され、指からの反射光に基づいて酸素飽和度の測定を行う光反射型のパルスオキシメータにも本発明は採用可能である。

【0074】

[2] 前記第1の実施形態や前記変形形態[1]では、指を本体部2と回動するカバー3とで挟み込む開閉タイプのパルスオキシメータ1を示したが、これに限らず、図14(a)、(b)に示すように、左右方向に貫通する貫通孔9'を有する筒体19を前記本体部2に一体的に設けたパルスオキシメータであっても、前記第1の実施形態と同様の効果が得られる。

【0075】

図14(a)は、本実施形態のパルスオキシメータ1'の外観を示す斜視図であり、図14(b)は、パルスオキシメータの一断面図である。図14(a)、(b)に示すパルスオキシメータ1'においても、左右どちらの側方(開口端)からでも指を前記貫通孔9'に挿入することができるため、前記第1の実施形態と略同様、どちらの手の指に装着する場合であっても、安定した装着状態で被験者は容易に測定結果を視認することができる。

【0076】

[3] 前記第1の実施形態では、カバー3が、前記本体部2に形成された支持軸8により回動自在に軸支された形態を示したが、このカバー3の回動機能に加えて、又は回動機能に代えて、カバーが本体部に対して上下方向に平行移動できるように構成するとさらに好ましい。図15は、カバーの回動と平行移動とが可能なパルスオキシメータ20の一例を示す図である。

【0077】

図15に示すように、パルスオキシメータ20は、前記第1の実施形態における本体部2と同様の機能を有する本体部21と、該本体部21の上部に設置されたカバー22とを有する。なお、図には表れていないが、測定結果を表示する表示部は、図15に示す本体部21の左側面に設置されている。

【0078】

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本体部21は、前記表示部が設置されている側と反対側(図15示す本体部21の右側)の側面における上端の左右両側部に、上方に突出する平板状の突出部21aを有し、この突出部21aに、上下方向に延びるガイド穴21a-1が形成されている。一方、カバー22の前記ガイド穴21a-1に対応する部位には、嵌合軸22aが突出形成されており、嵌合軸22aが前記本体部21のガイド穴21a-1に嵌合している。

【0079】

ガイド穴21a-1は、上下方向に前記嵌合軸22aの径より長い為、前記嵌合軸22aは、ガイド穴21a-1内を上下方向に移動可能となり、これにより、カバー22は、本体部21に対して対接及び離反する方向(上下方向)に平行移動可能となっている。また、カバー22は、嵌合軸22aを中心として回転可能となっている。

【0080】

また、前記第1の実施形態と同様、本体部21は、その上面に左右方向に延びる凹部21bを有している一方、前記本体部21の上面と対向するカバー22の部位には、前記切欠き部3a、3bと略同様の切欠き部22bが形成されており、本体部21とカバー22とが最も近接するとき、この切欠き部22bと前記凹部21bとにより、指が嵌め込まれる貫通孔23が形成される。

【0081】

図15に示す構成では、カバー22が回転する構成とカバー22が本体部21に対して対接離反方向に平行移動する構成とを併せ持つが、本件は、例えば図16に示すように、カバー22が回転する機能を有さず、カバー22が本体部21に対して対接離反方向に平行移動する機能のみを有するパルスオキシメータも含む。図16(a)は、このパルスオキシメータの一例を示す側面図、図16(b)は、図16(a)の矢印Yから見た平面図である。

【0082】

図16(a)、(b)に示すパルスオキシメータ30は、図15に示すパルスオキシメータ20における本体部21と同様の本体部31と、該本体部31の上部に設置されたカバー32とを有する。なお、図には表れていないが、測定結果を表示する表示部は、図16に示す本体部31の左側面に設置されている。

【0083】

本体部31は、前記表示部が設置されている側と反対側(図16の本体部21の右側)の側面における上端部に、平面視で(矢印Yの方向からみて)中空の矩形状の延設部31aを有するとともに、この延設部31aの左右方向(図16(b)では上下方向)における各内壁面の所定位置に、上下方向に延びるガイド溝31a-1がそれぞれ形成されている。一方、カバー32の前記ガイド溝31a-1に対応する部位には、矩形状の断面を有するレール部32aが上下方向に延びるように形成されており、レール部32aが前記本体部31のガイド溝31a-1に嵌合している。

【0084】

これにより、カバー32が本体部31に対して、レール部32aとガイド溝31a-1との嵌合を介してスライド可能となり、カバー32は、本体部31に対して対接離反方向に平行移動することができる。

【0085】

また、前記第1の実施形態や図15に示す構成と同様、本体部31は、その上面に左右方向に延びる凹部31bを有している一方、前記本体部31の上面と対向するカバー32の部位には、前記切欠き部3a、3b等と略同様の切欠き部32bが形成されており、本体部31とカバー32とが最も近接するとき、切欠き部32bと前記凹部31bとにより、指が嵌め込まれる貫通孔33が形成される。

【0086】

このように、カバー3が平行移動可能に構成することで、前記第1の実施形態に比して次のような利点を有する。

【0087】

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前記第1の実施形態のバルスオキシメータ1に着目したとき、本体部2及びカバー3は、指に対して互いに反対側の位置（対向する位置）で該指Fに接触して該指Fを挟み込む状態が、最も安定した装着状態となる。ここで、バルスオキシメータ1を前記左右方向（厚み方向）に薄型化するために、支持軸8を、図3における左右方向においてできるだけ指の近傍に配置（支持軸8を図3の左側に配置）した場合、被験者の指の太さによっては、本体部2及びカバー3が指Fに対して互いに反対側の位置で該指Fに接触して該指Fを挟み込むことができず、本体部2及び指Fの接触位置とカバー3及び指Fの接触位置とが、該指Fの周方向における或る部位に偏り、バルスオキシメータ1の装着状態が不安定になることが考えられる。

【0088】

そこで、本実施形態のように、カバー32は、本体部31に対して対接離反方向に平行移動することができるようにすることで、本体部2及びカバー3が指Fにおける互いに反対側の位置（対向する位置）で該指Fに接触して該指Fを挟み込むようにすることができる。その結果、バルスオキシメータ1の薄型化を図りつつ、バルスオキシメータ1を指Fに安定して装着することができる。

【0089】

〔4〕指を測定部位として酸素飽和度を測定する場合に、発光部及び受光部の設置位置に爪の根元が位置する状態で測定すると、発光部及び受光部の設置位置に他の部位が位置する場合に比して、高い精度で酸素飽和度が測定できることが知られている。しかしながら、特に、側方から指を挿入するタイプである例えば図14に示すバルスオキシメータ1'にあっては、貫通孔9'を直線的に延びる形状に形成した場合、該貫通孔9'に対する指の位置決めがなされないため、測定時における爪の根元の位置と発光部及び受光部の設置位置との位置関係が測定毎に不定であり、また、発光部及び受光部を外部から視認し難いことから、被験者が爪の根元を発光部及び受光部の設置位置に位置させることは困難である。そこで、次のような構成を採用するとよい。

【0090】

例えば図14に示すバルスオキシメータにおいて、図17に示すように、貫通孔9'の形状を、装着対象の指Fの関節による指の曲げ方向に逆らって該指Fの腹の部分が反る方向に湾曲した凹形状に形成するとともに、前記貫通孔9'の略最下点に発光部7及び受光部5を設置するとよい。

【0091】

この場合、指Fを本体部2の上面に腹の部分が接触するように前記貫通孔9'内に挿入すると、指の構造上、爪の根元が自然にほぼ貫通孔9'の最下点に位置することとなる。これにより、高い酸素飽和度の測定精度を確保することができる。なお、貫通孔9'の形状は、図17に示すように、曲線状に形成してもよいし、あるいはV字形状に形成してもよい。

【0092】

〔5〕前記第1の実施形態では、直方形状を有する本体部2の一外壁面に表示部が設けられたバルスオキシメータについて説明したが、本件は、この形態に限らず、例えば図18に示すように、バルスオキシメータ1が全体として円柱状の周面（外壁面）を有する形状に構成されており、その周面に表示部34が設置されている場合には、該円柱の中心軸Lの方向に貫通する貫通孔35を形成する形態も含む。

【0093】

さらに、バルスオキシメータの全体的な形状が、装着時の指の長手方向に略直交する面による断面に着目したときに、前記第1の実施形態のような四角形以外の多角形（例えば三角形や六角形）の断面をなす形状である場合において、その断面を構成する複数の周面（外壁面）のうち一の周面に表示部が設置されている場合には、その表示部の表示面に略沿って貫通孔を形成するとよい。

【0094】

例えば図19（a）に示すように断面が三角形形状を有するバルスオキシメータの場合に

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において、周面36～38のいずれか1つの周面に表示部が設置されているとき、この表示部の表示面に略沿う方向（紙面の表裏方向）に延びる貫通孔39を形成する形態を想定できる。

【0095】

また、例えば図19（b）に示すように、断面が六角形状を有するパルスオキシメータの場合において、周面40～45のいずれか1つの周面に表示部が設置されているとき、この表示部の表示面に略沿う方向（紙面の表裏方向）に延びる貫通孔46を形成する形態を想定できる。

【0096】

さらに、図20に示すように、パルスオキシメータの全体的な形状が球状である場合において、その周面47の所定位置に表示部48が設置されているとき、その表示部48の表示面に略沿って貫通孔49を形成する形態も想定できる。

【0097】

〔6〕生体情報測定装置の一例としてのパルスオキシメータに本発明を採用した構成を前記各実施形態として説明したが、本発明は、パルスオキシメータに限らず、心臓の拍動に起因する脈波を測定する光電脈波計にも採用可能である。

【図面の簡単な説明】

【0098】

【図1】パルスオキシメータの外観を示す斜視図である。

【図2】パルスオキシメータの一断面図である。

【図3】図2におけるA-A線からみた矢視断面図である。

【図4】パルスオキシメータの電気的な構成を示すブロック図である。

【図5】ヘモグロビン及び酸化ヘモグロビンの吸光特性を示すグラフである。

【図6】生体による光の吸収を示す図である。

【図7】生体に入射する入射光と透過光との関係を模式的に表す図である。

【図8】赤外光による透過光量の正規化を説明するための図である。

【図9】吸光係数の比と酸素飽和度との関係を示す図である。

【図10】パルスオキシメータにおける測定結果の表示処理を示すフローチャートである。

【図11】第1の実施形態の効果を説明するための図である。

【図12】本発明の他の実施形態の説明図である。

【図13】本発明の他の実施形態の説明図である。

【図14】本発明の他の実施形態の説明図である。

【図15】本発明の他の実施形態の説明図である。

【図16】本発明の他の実施形態の説明図である。

【図17】本発明の他の実施形態の説明図である。

【図18】本発明の他の実施形態の説明図である。

【図19】本発明の他の実施形態の説明図である。

【図20】本発明の他の実施形態の説明図である。

【図21】従来のパルスオキシメータの説明図である。

【図22】従来のパルスオキシメータに発生する問題点を示す図である。

【符号の説明】

【0099】

1, 20, 30 パルスオキシメータ

2, 21, 31 本体部

2c, 31b 凹部

3, 22, 32 カバー

3a, 21b, 31b 凹部

3c 嵌合部

4 表示部

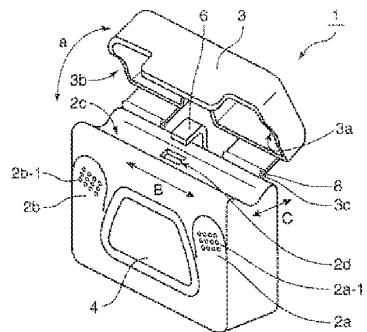
5 受光部

(1 4)

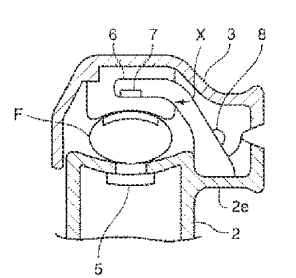
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- 6 アーム
- 7 発光部
- 8 支持軸
- 9, 23, 33, 35, 39, 46, 49 貫通孔
- 10 測定部
- 13 制御部
- 16 酸素飽和度演算部
- 19 筒体
- 21a ガイド穴
- 22a 嵌合軸
- 22b, 32b 切欠き部
- 31a ガイド溝
- 32a レール部

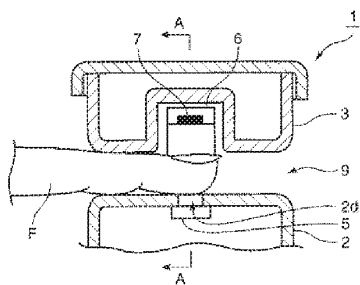
【図1】



【図3】



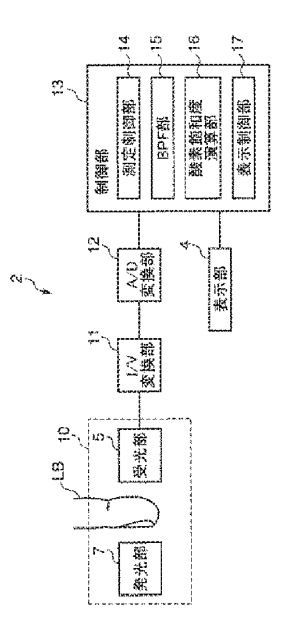
【図2】



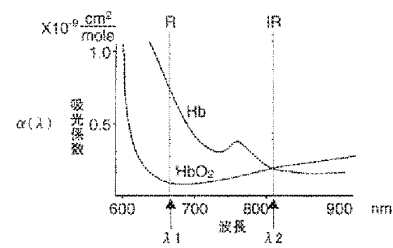
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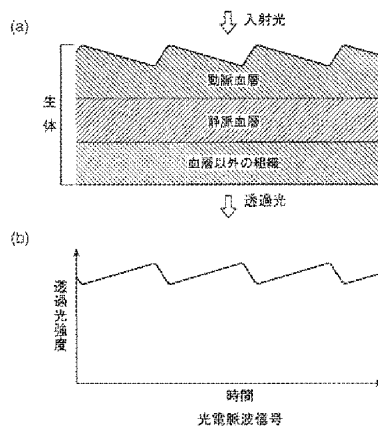
【図4】



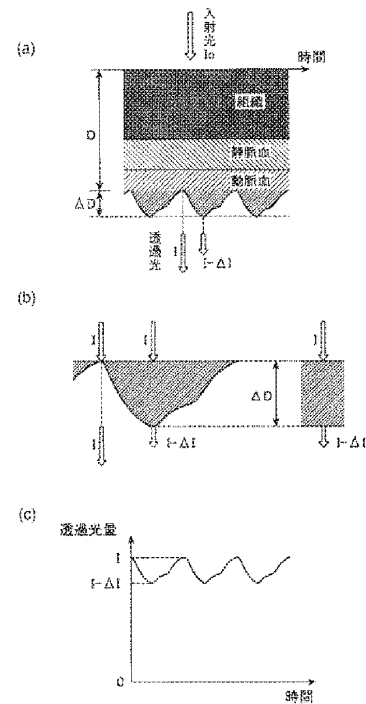
【図5】



【図6】



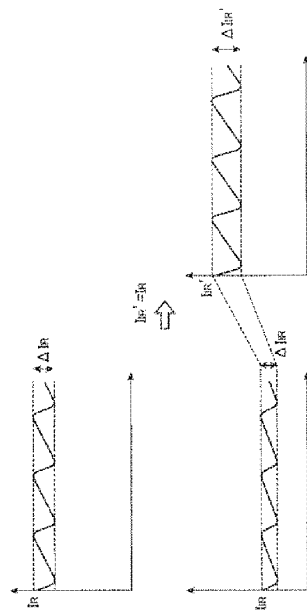
【図7】



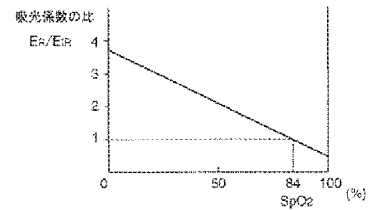
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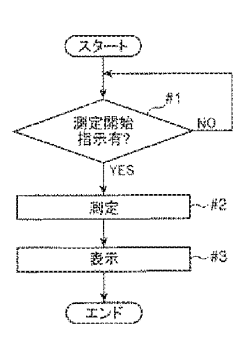
【図8】



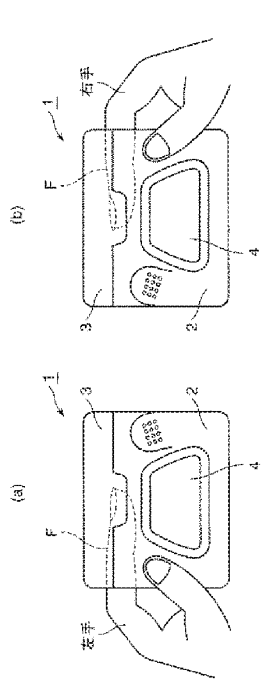
【図9】



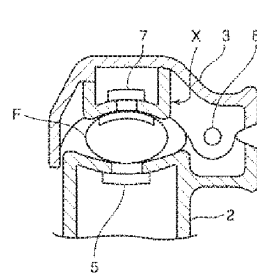
【図10】



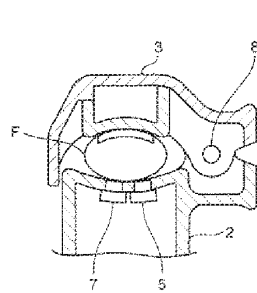
【図11】



【図12】



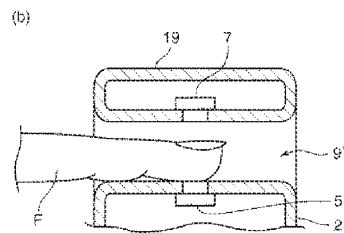
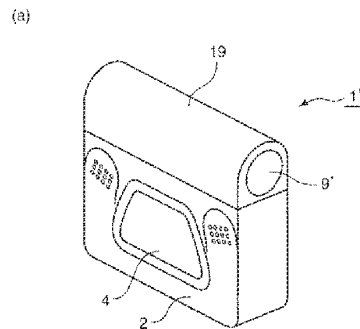
【図13】



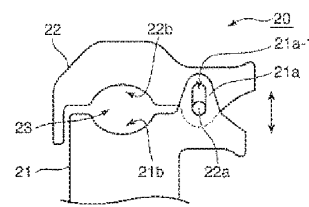
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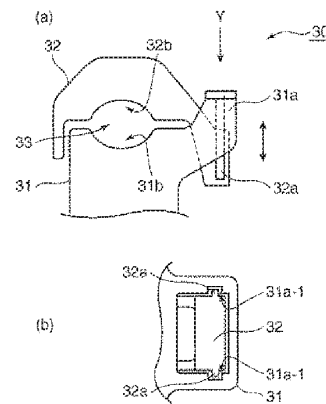
【図14】



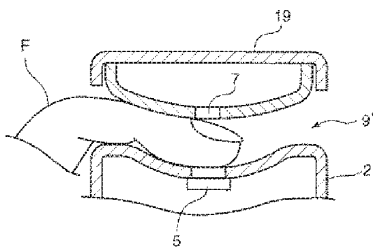
【図15】



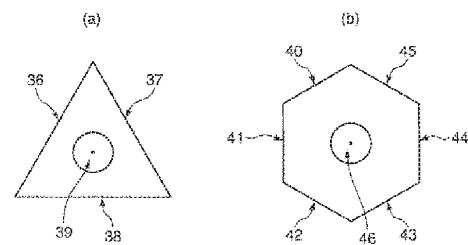
【図16】



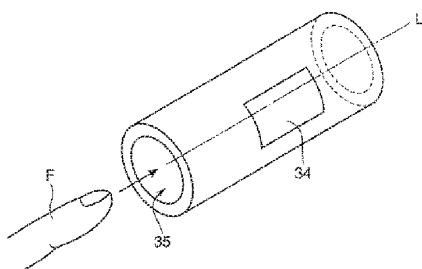
【図17】



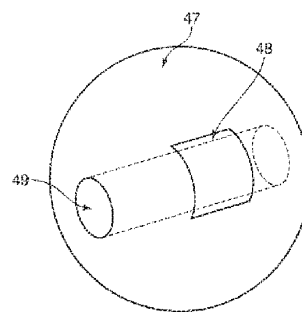
【図19】



【図18】



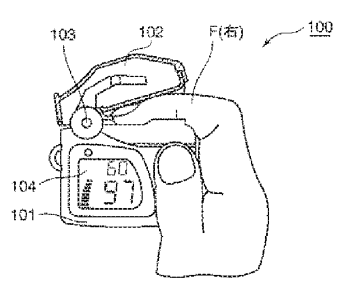
【図20】



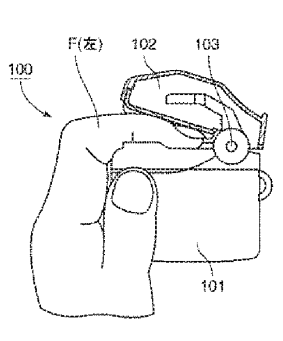
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【図21】



【図22】



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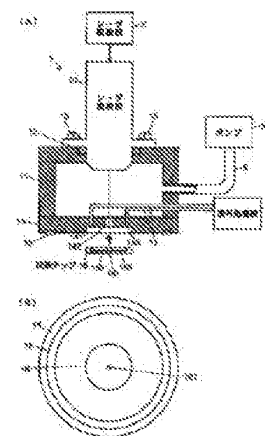
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 (71)Applicant SHIMADZU CORP
 (72)Inventor HAYASHI HIDEMIKI

(54)ORGANISM MEASURING DEVICE**(57)Abstract**

PROBLEM TO BE SOLVED: To simply measure blood sugar with high accuracy without giving pain to a subject.

SOLUTION: From a laser radiating part 10 fixed to an upper cover 11, laser light is radiated toward a micro-opening 161 of a replacement chip 16 removably fitted to a lower cover 14, and a very small hole is bored in the skin of a peeping region in the micro-opening 161. After that, immediately a tissue liquid is leached out of the hole by suction of a pump 3, and the glucose concentration in the tissue liquid is measured by enzyme electrodes 162, 163a little projected into the micro-opening 161.

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(19) 日本国特許庁 (J P)

(12) 公開特許公報 (A)

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(P2003-265444A)

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(51) Int.Cl.⁷

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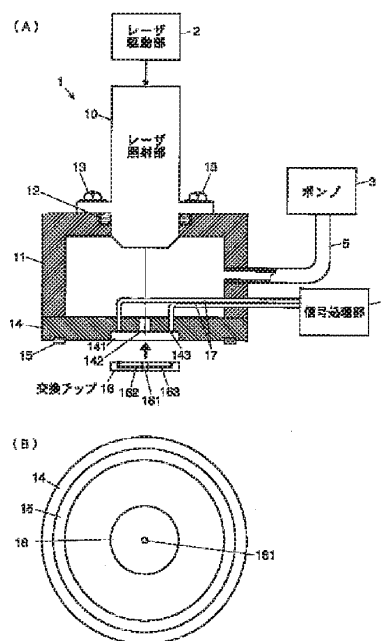
Fターム(参考) 4C038 KK10 KL01 KL09 KM01 KX01
TA04 UG10

(54) 【発明の名称】 生体計測装置

(57) 【要約】

【課題】 被検者に痛みを与えることなく簡便で精度の高い血糖測定を行う。

【解決手段】 上蓋11に固定されたレーザー照射部10から、下蓋14に着脱自在に嵌合された交換チップ16の微小開口161に向けてレーザー光を照射し、微小開口161に覗く部位の表皮に微小穴を開ける。その後すぐにポンプ3による吸引により穴から組織液を浸出させ、微小開口161内に僅かに突出した酵素電極162、163により組織液中のグルコース濃度を測定する。



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【特許請求の範囲】

【請求項1】 a) 生体表面に接触する接触面に微小開口を有する接触体と、
b) 該接触体に対して位置が固定され、前記接触面が生体表面に接触した状態で前記微小開口に露出する部位に対しレーザ光を照射するレーザ照射手段と、
c) 該レーザ光が照射された部位から前記微小開口を介して組織液を吸引する吸引手段と、
d) 該吸引手段により吸引された組織液に接触するように設けられた一対の酵素電極を含み、該組織液中の成分に関連する生体情報を測定する測定手段と、
を備えたことを特徴とする生体計測装置。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】 本発明は、例えば血糖値の測定などに好適な生体計測装置に関する。

【0002】

【従来の技術】 従来、血糖値を測定する方法として、生体の一定深さまで針を刺して吸引により組織液を採取し、その組織液中の糖濃度（グルコース濃度）を測定するという方法が知られている。しかしながら、このような方法では、真皮層まで針が挿入されてしまうため、被検者に与える身体的苦痛が大きい。また、マイクロダイアリス法と呼ばれる組織液の採取方法も知られているが、測定可能な組織液量を採取するのに時間を要するのに加え、作業が面倒であり、被検者に与える身体的苦痛も小さくはない。

【0003】 これに対し、被検者に与える身体的苦痛をできるだけ軽減するために、生体表面にレーザ光を照射して生体の表皮まで微小な穴を開けた後、その穴から組織液を吸引することにより採取し、その組織液中の糖濃度を測定する技術も、米国のスペクトラクス社（SpectRx社）より提案されている。

【0004】

【発明が解決しようとする課題】 こうした測定方法は穿刺法に代わる有用な方法の一つであると考えられる。しかしながら、実際には、生体表面は弾性を有するとともに随意及び不随意的動きがあるため、レーザ光の焦点位置を決めるのが難しく、焦点位置が生体表面から深さ方向にずれてしまうと、適切に表皮まで穴を開けることができなったり、逆に生体組織に意図しない損傷を与えてしまったりするおそれがある。

【0005】 また、レーザ光で表皮に微小穴を開けた後、組織液を吸引するために別の装置を装着し、更には、採取した組織液をまた別の装置で測定する必要がある。そのため、組織液の採取から測定までに時間が経過してしまい、組織液中の水分が蒸発したり成分が変性したりして、糖濃度の測定精度が劣化してしまうという問題がある。また、そもそも、上記のような手順の測定は大変面倒であって、測定作業の効率に劣るものである。

【0006】 本発明はこのような点に鑑みて成されたものであり、その主たる目的とするところは、被検者に身体的苦痛を与えることなく、しかも高い精度で且つ高い再現性をもって組織液中の各種成分の測定を行うことができる生体計測装置を提供することにある。

【0007】

【課題を解決するための手段】 上記課題を解決するために成された本発明に係る生体計測装置は、

a) 生体表面に接触する接触面に微小開口を有する接触体と、
b) 該接触体に対して位置が固定され、前記接触面が生体表面に接触した状態で前記微小開口に露出する部位に対しレーザ光を照射するレーザ照射手段と、
c) 該レーザ光が照射された部位から前記微小開口を介して組織液を吸引する吸引手段と、
d) 該吸引手段により吸引された組織液に接触するように設けられた一対の酵素電極を含み、該組織液中の成分に関連する生体情報を測定する測定手段と、
を備えたことを特徴としている。

【0008】

【発明の実施の形態、及び効果】 本発明に係る生体計測装置を用いた測定を行う際には、接触体の接触面を被検者の皮膚表面に密着させる。すると、微小開口の内側に被検者の皮膚表面が覗く。皮膚は弾性を有しているため、微小開口の内側では皮膚表面が盛り上がるが、その開口の面積は小さいため、盛り上がり部分の高さは小さい。そのため、レーザ照射手段によるレーザ光の焦点位置と皮膚表面との深さ方向のずれは小さくて済み、表皮のみにごく微小な穴を開けることができる。被検者の表皮に穴が開いた直後に、吸引手段はこの穴から組織液を吸い上げる。吸引手段としては例えばポンプなどを用いることができる。吸引によって浸出した組織液は微小開口に近接して設けられている一対の酵素電極の間に満ち、これにより、測定手段は組織液中の成分に関連する生体情報、例えば糖濃度などを測定する。

【0009】 なお、吸引手段により穴から吸い出された組織液を酵素電極に導くために、例えば毛細管作用などを利用してもよい。

【0010】 このように本発明に係る生体計測装置によれば、まず、レーザ光を正確に生体表面に集光して穴開けを行うことができるので、確実に微小な穴を開けることができ、不所望に生体を損傷することも防止することができる。また、生体から浸出した組織液を時間をおくことなく速やかに測定することができるため、組織液中の成分の変性や水分の蒸発などがなく、正確な測定が行える。更には、本発明に係る生体計測装置によれば、測定作業が非常に簡単であり、効率的な測定が行える。

【0011】 なお、好ましくは、微小開口を含む接触面の一部と、組織液が接触する酵素電極とを一体化し、交換自在の構成とする。この構成によれば、被検者

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の組織液が付着する部分を測定毎に容易に交換することができるので、衛生的であって不所望の感染などを防止することができる。

【0012】

【実施例】以下、本発明に係る生体計測装置の一実施例について、図1～図3を参照して説明する。図1(A)は本実施例による生体計測装置のサンブラを縦断面図で示す全体構成図、図1(B)はサンブラの下面図、図2はサンブラの要部の拡大図、図3は測定時の状態を示す図である。

【0013】図1(A)に示すように、本実施例の生体計測装置は、被検者の身体表面に接触されるサンブラ1と、レーザ駆動部2と、ポンプ3と、信号処理部4とを備える。サンブラ1では、有蓋円筒形状の上蓋11の上面に、レーザ照射部10が気密用のリング12を挟んでネジ13で固定されている。上蓋11の下面開口には、円盤状で中央に凹陥部141と貫通穴142とを有する下蓋14が接着されている。下蓋14の下面の外周側にはシリコンゴムから成る円環状の滑り止め部材15が装着されており、中央の凹陥部141には円盤状の交換チップ16が嵌め込まれる。この交換チップ16の下面と下蓋14の下面とは面一になっており、これが生体表面への接触面となる。

【0014】上蓋11の側面にはポンプ3に至る吸気管5が接続されている。また、下蓋14には、後述の酵素電極による検知信号を信号処理部4へ送るための信号ケーブル線17の端部が埋設されており、この信号ケーブル線17の導電体は凹陥部141内に露出する薄板状の接点部143に接続されている。

【0015】図2に示すように、交換チップ16は中央に上下に貫通した微小開口161を有し、該微小開口161内に僅かに突出して一対の酵素電極(固定化酵素電極)162、163が埋設されている。酵素電極162、163の他端はそれぞれ交換チップ16の上面に露出しており、交換チップ16が下蓋14の凹陥部141に嵌め込まれると、上記接点部143に面接触する。これにより、酵素電極162、163と信号処理部4との間の電気的導通が確保される。

【0016】酵素電極162、163は周知のように、白金などの金属電極の表面に酵素固定化膜や選択透過膜などを形成したものであり、ここでは、酵素固定化膜としてグルコースオキシダーゼ(GOD)を用いることにより、組織液中のグルコース濃度を測定する。その原理は、GODが組織液中のグルコースを酸化し、それによって発生する過酸化水素が白金表面で電気分解する際に流れる電流を検出するものである。

【0017】続いて、上記構成の生体計測装置を用いた測定手順と動作について、図3により説明する。

【0018】測定時には、サンブラ1の接触面を被検者の皮膚6に適度な圧力で押し当てる。下面に突出した滑

り止め部材15が皮膚を押圧し大きな摩擦を与えるので、それほど強く押し当てなくとも横ずれがしにくい。このようにしたとき、微小開口161の内側に覗いた皮膚は若干盛り上がるが、開口面積が小さいため、その盛り上がりは殆ど無視できる程度に小さい。したがって、レーザ照射部10の照射面から皮膚表面までの距離は常にほぼ一定になり、レーザ光の焦点Fが皮膚表面から所定の深さ位置になるように正確に決めることができる。これによって、確実に表皮に微小穴を開けることができ、被検者の身体深部を損傷するおそれもなく、痛みを感じさせることもない。

【0019】レーザ駆動部2からの指示により、レーザ照射部10は貫通穴142及び微小開口161に覗いた部位にレーザ光を短時間照射する。なお、レーザ光としては、例えば水の吸収波長ピークに近い1480nmの波長を使用するとよい。レーザ光の照射によって、表皮には微小穴が開く。また、レーザ照射とほぼ同時又は僅かに前後して、ポンプ3による吸引を開始する。

【0020】この吸引により、上蓋11及び下蓋14で囲われた気密室内は負圧になり、先に開けられた表皮の微小穴から組織液が吸い上げられる。体外に浸出した組織液は微小開口161内部に充満し、酵素電極162、163に接触する。組織液中のグルコースとの上記原理のような反応により酵素電極162、163間には電流が流れるから、信号ケーブル線17を介して信号処理部4はこの電流を検出し、所定のアルゴリズムに従ってグルコース濃度を算出する。組織液量は酵素電極162、163に接触する程度で充分であり、上記気密室内にまで組織液が入ってゆくことはあまり好ましくないから、ポンプ3は穴開け後に所定の短時間経過したときに運転を停止するとよい。

【0021】こうして測定を終了したならば交換チップ16を取り外し、次の測定の際には、別の新品の交換チップを装着する。これにより、或る被検者の組織液が他の被検者の表皮に開けた穴から侵入することを防止でき、高い衛生性を確保することができる。

【0022】なお、上記実施例は本発明の単一例に過ぎず、本願の特許請求の範囲に記載の趣旨の範囲で、様々な形態や構成に変形・修正できることは明白である。例えば、交換チップ16の電極と信号ケーブル線との接続はコネクタ式など他の方法でもよい。また、交換チップ16の脱着方法も各種形態に変形できる。また、酵素電極は微小開口内に突出するものでなくとも、微小開口に浸出して来た組織液を速やかに酵素電極に導く構成でありさえすればよく、例えば毛細管作用を利用して、微小開口から横方向に組織液を導くようにしてもよい。

【図面の簡単な説明】

【図1】 本発明の一実施例による生体計測装置におけるサンブラを縦断面図で示す全体構成図(A)及びサンブラの下面図(B)。

(4) 003-265444 (P2003-265444A)

【図2】 サンプラの要部の拡大図。

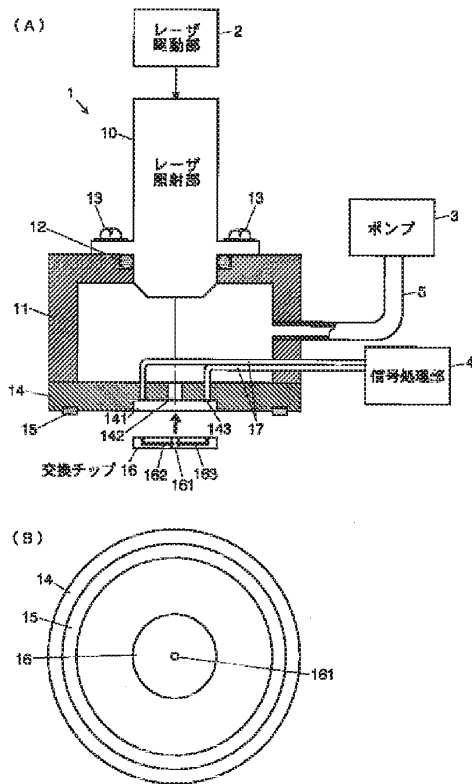
【図3】 測定時の状態を示す図。

【符号の説明】

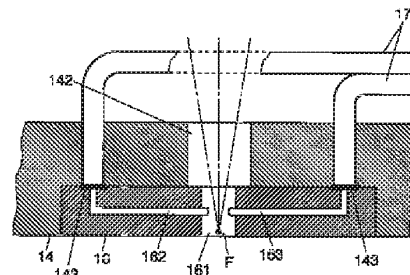
1…サンプラ
10…レーザー照射部
11…上蓋
12…Oリング
13…ネジ
14…下蓋
141…凹陥部
142…貫通穴

143…接点部
15…滑り止め部材
16…交換チップ
161…微小開口
162…酵素電極
17…信号ケーブル線
2…レーザー駆動部
3…ポンプ
4…信号処理部
5…吸気管

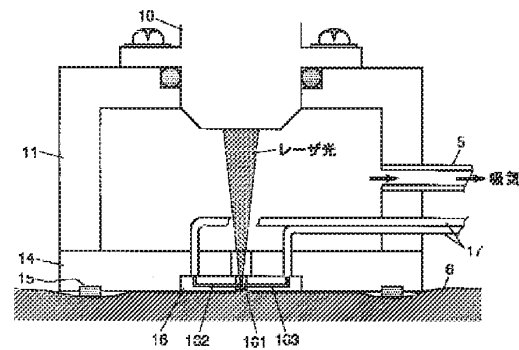
【図1】



【図2】



【図3】

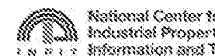


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(54)ELECTRODE PLATE FOR ALKALINE STORAGE BATTERY AND ITS MANUFACTURE

(57)Abstract

PURPOSE: To provide a battery which is excellent in a life characteristic by limiting the quantity of a phosphorus element contained in the metal porous body of a positive electrode, thereby preventing the corrosion of the metal porous body due to the repetition of a charge and discharge cycle and suppressing the lowering of a charge and discharge characteristic accompanying it.

CONSTITUTION: In this alkaline storage battery, a power generation component is constituted of a positive electrode in which an active material using a metal oxide as a main body is held in a metal porous body, a negative electrode, an alkaline electrolytic solution and a separator.

The quantity of a phosphorus element contained in the metal porous body of the positive electrode is limited to not more than 0.10wt.% relative to the weight of the metal porous body.

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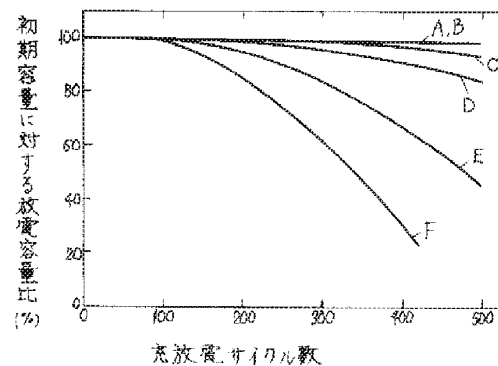
(74) 代理人 弁理士 小銀治 明 (外2名)

(54) 【発明の名称】 アルカリ蓄電池用極板およびその製造法

(57) 【要約】

【目的】 金属酸化物を主体とする活物質を金属多孔体に保持させたアルカリ蓄電池用極板において、金属多孔体を改善することにより、充放電に伴う内部抵抗の上昇を抑制し、寿命特性に優れた電池を提供する。

【構成】 金属多孔体に含まれるリン元素の量を金属多孔体重量に対し0.10重量%以下とした。



(2)

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【特許請求の範囲】

【請求項1】金属酸化物を主体とする活物質を金属多孔体に保持させた正極と、負極と、アルカリ電解液と、セパレータとから構成された発電要素において、前記正極の金属多孔体に含まれるリン元素の量が金属多孔体重量に対し0.10重量%以下であることを特徴とするアルカリ蓄電池用極板。

【請求項2】金属多孔体がスポンジ状ニッケル多孔体であり、このスポンジ状ニッケル多孔体は、その基材となるスポンジ状有機物多孔体の表面にニッケルメッキし、その後前記スポンジ状有機物を燃焼除去して得たものであって、ペースト状活物質をこの金属多孔体に充填することを特徴とするアルカリ蓄電池用極板の製造法。

【発明の詳細な説明】

【0001】

【産業上の利用分野】本発明は、アルカリ蓄電池用極板およびその製造法に関するものである。

【0002】

【従来の技術】アルカリ蓄電池の代表的なものに、ニッケル・カドミウム蓄電池（以下ニカド電池と記す）が挙げられる。ポータブル機器の電源としてニカド電池と鉛蓄電池とを比較した場合、ニカド電池は、単位重量および単位体積当たりのエネルギー密度が高く、サイクル寿命等の信頼性に優れている。そのため種々のポータブル機器の電源として広く用いられている。

【0003】しかし、ポータブル機器用の電源としてニカド電池と同等の信頼性を有し、さらに高いエネルギー密度を持つ蓄電池が切望されている。近年、このニカド電池の1.3倍以上の電池容量を有する高容量ニカド電池や、ニカド電池のカドミウム負極に代えて、電気化学的に多量の水素の吸蔵・放出反応（充放電反応）が可能な水素吸蔵合金を用いたニッケル・水素蓄電池、あるいは負極に亜鉛を用いたニッケル・亜鉛蓄電池が注目されている。

【0004】これらアルカリ蓄電池に共通して使用されているニッケル正極は、焼結式あるいはペースト式の電極が用いられている。特にスポンジ状ニッケル多孔体には、ニッケル酸化物を主体としたペースト状活物質を充填したペースト式正極の極板の容量密度は、600mAh/c以上に達する。そのため、このようなペースト式正極を用いたアルカリ蓄電池では、従来のニカド電池と比べ、1.6倍以上の容量を得ることができ、高エネルギー密度化が可能となる。

【0005】このスポンジ状ニッケル多孔体は、一般的にはスポンジ状ウレタン等のスポンジ状有機物多孔体に電気伝導性を付与し、ニッケルを電気メッキした後、スポンジ状有機物を燃焼除去することによって得られる。このスポンジ状有機物多孔体に電気伝導性を付与する方法としては、カーボン、ニッケル等の導電性物質を塗布する方法（例えば、特開平4-229955号公報）

や、真空蒸着する方法（例えば、特開昭64-24365号公報）、化学メッキする方法（例えば、特開昭56-102076号公報）などがある。

【0006】このうち、塗布法は塗布される導電性物質の均一性の面で課題がある。具体的には、スポンジ状有機物多孔体に均一に導電性が付与されないと、ニッケルの電気メッキ工程においてメッキムラが生じ易くなり、ニッケル多孔体の重量バラツキが大きくなる。更に、得られたニッケル多孔体の機械的強度、導電性が低下する。

【0007】一方、真空蒸着法は、ニッケルの厚みの均一性は良いが、コストの面で課題がある。このため、化学メッキ法が均一性、コストの両面から、最も有効であると考えられる。

【0008】

【発明が解決しようとする課題】しかし、前述した化学メッキ、特にリン酸型メッキ浴による化学メッキ法では、カーボン等の導電性物質を塗布する方法と比べ、充放電サイクルの繰返しに伴い、電池の内部抵抗が増大し易く、放電特性および寿命特性の低下を引き起こすという課題があった。この原因はいまだ明らかではない。しかしこの手法で作成したニッケル等の金属多孔体を集電体として電池を構成した際、メッキ浴を構成する元素、特にリン等が不純物として金属多孔体中に残存するため、充放電過程において、ニッケル多孔体に対しこれら元素が何らかの悪影響を及ぼす。その結果、ニッケル多孔体の腐食を促進し、金属多孔体の抵抗が増大するためであると推測される。

【0009】更に、前述した他の電気伝導性の付与方法、例えば導電性物質を塗布する方法などでも、多孔体にニッケルを電気メッキする際、界面活性剤、レベリング剤等としてリン化合物を用いることが多い。そのため、化学メッキ法と同様の課題を有していた。

【0010】本発明は、上記課題を解決するもので、金属多孔体に含まれる不純物、特にリンを規定含有量以下に維持することにより、充放電サイクルの繰返しによる金属多孔体の腐食を防止し、それにとまう放電特性低下を抑制し、寿命特性の優れた電池を提供することを目的とするものである。

【0011】

【課題を解決するための手段】上記目的を達成するために本発明は、金属多孔体中に含まれるリン元素の含有量が多孔体自身の重量に対し0.10重量%以下であり、更に望ましくは、この金属多孔体がスポンジ状ニッケル多孔体であって、その基材となるスポンジ状有機物多孔体表面にニッケルメッキを施し、その後、前記スポンジ状有機物を燃焼除去して得られたことを特徴とするものである。

【0012】

【作用】このように正極活物質の集電体である金属多孔

(3)

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体に含まれるリン元素の含有量を規定量以下、具体的には金属多孔体重量に対し0.10重量%以下に制限することにより、充放電サイクルの繰返しに伴う金属多孔体の腐食を抑制できる。その結果、正極の分極に起因する放電特性の低下が抑制でき、寿命特性が向上する。

【0013】

【実施例】以下、発明の詳細を図面とともに説明する。尚、本実施例では、金属多孔体としてスポンジ状ニッケル多孔体を用い、ニッケル・水素蓄電池を例に用いて説明する。

【0014】スポンジ状ニッケル多孔体は以下の手順に従って作製した。まず、厚さ約1.5mmのスポンジ状ウレタンを界面活性剤によって親水化処理し、水洗した後、塩化パラジウムと塩化第一スズの塩酸溶液中に浸漬した後、水洗を行い、さらに塩酸浸漬、水洗を施すことによって化学メッキのためのパラジウム核を均一に形成させた。次に、ニッケル次亜リン酸型の化学メッキ浴に浸漬してニッケルの化学メッキを行い、スポンジ状ウレタンに電気伝導性を付与した。これを水洗、乾燥させた後、ワット浴中でニッケルの電気メッキを行った。ついで約800℃の水素雰囲気炉で加熱することによって、スポンジ状ウレタンの樹脂芯体を炭化除去し、三次元網状構造を有するスポンジ状ニッケル多孔体を作成した。この時、スポンジ状ニッケル多孔体中のリン含有量は、化学ニッケルメッキ量、および化学メッキ後の水洗の条件を変化させることによって調整し、原子吸光分析により定量した。

【0015】このようにして得られたスポンジ状ニッケル多孔体は、平均多孔度約95%、平均孔径約500ミクロン、平均ニッケル格子径約50ミクロン、面密度（単位面積当たりのニッケル量）約500g/m²であった。

【0016】尚、前記多孔体の製造工程において、リン化合物の添加は、化学メッキ工程以外、具体的には電気メッキ工程においてのレベリング剤等としてのリン化合物の添加は、行わなかった。

【0017】ペースト式正極とするため、このスポンジ状ニッケル多孔体に、平均粒子径が約10μmの水酸化ニッケル粉末100重量部に対し、平均粒子径が約3μmの水酸化コバルト粉末6重量部と水とを混合した活物質ペーストを充填した。このスポンジ状ニッケル多孔体を、乾燥、プレスした後、フッ素樹脂のディスパージョンに浸漬乾燥して所望の寸法に切断したものを用いた。

【0018】一方、負極に用いた水素吸蔵合金電極には、CaCu₂型の結晶構造を有する、組成式MmNi_{3.55}Mn_{0.4}Al_{0.8}Co_{0.75}（Mmは希土類元素の混合物）の水素吸蔵合金をボールミルによって平均粒子径約20μmの微粉末とし、KOH溶液中で浸漬処理、水洗を行い、水と混合してペースト状にした後、面密度650g/m²で多孔度約95%のスポンジ状ニッケル多孔

体に所定量を充填、乾燥、プレス後、所望の寸法に切断したものを用いた。

【0019】次に、上記ペースト式の正、負極と、親水化処理したポリプロピレン製の不織布からなるセパレータとを組み合せ、これを渦巻状に巻回し電池を構成した。負極には、その理論容量が正極の1.5～1.6倍、その長さが正極の長さに35mmを加えた負極との組合せを渦巻状に巻回し、容量1500mAhの4/5Aサイズの密閉電池を構成した。なお、電解液には比重1.30のKOH水溶液にLiOH・H₂Oを40g/L溶解させたものを用い、これを1セル当たり2.5cc注液した。

【0020】本発明で作成した電池の正極のスポンジ状ニッケル多孔体中におけるニッケル重量に対するリン含有量を、表1に示す。尚、表1の電池番号Aのリン含有量=0重量%のスポンジ状ニッケル多孔体は、スポンジ状ウレタンへの導電性付与法として化学メッキ法でなく、カーボン塗布法を採用した。

【0021】

【表1】

電池番号	金属多孔体重量に対するリン元素の量
A	0 重量%
B	0.01 重量%
C	0.05 重量%
D	0.10 重量%
E	0.20 重量%
F	0.40 重量%

【0022】表1のA～Fの6種類の電池を、20℃の雰囲気下で24時間放置した後、予備充放電を行い、寿命試験に供した。この時の試験条件は、40℃の雰囲気下で、充電を1.5Aで72分間行った後、放電を1.5Aで1.0Vまで行った。この寿命試験温度として40℃を選んだのは、特性の劣化原因が充放電サイクルの繰返しに伴うニッケル多孔体の腐食に起因すると仮定した場合、想定される電池使用温度範囲（約0℃～40℃）の中で劣化が、最も加速される温度と考えられるためである。

【0023】図1にそれぞれの電池の、充放電サイクル数と初期容量に対する放電容量比率との関係を示した。

【0024】図1から明らかなように、正極のスポンジ状ニッケル多孔体中のリン含有量が少ないほど、充放電サイクルに伴う放電容量の低下が小さく、電池用電極の

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基材として適していることが判かる。

【0025】また、電池Aに用いたリンを含有していないスポンジ状ニッケル多孔体中に、電池B～Fの多孔体中に含まれている量に相当するリン酸を添加した場合、前記寿命試験における電池B～Fの値とは一致しないが、リン酸の添加量の増加に伴い寿命特性が、低下することも確認できた。

【0026】更に、スポンジ状ウレタンへの導電性付与方法として、本実施例の化学メッキ法ではなく、カーボン塗布法を用いた場合、ニッケル電気メッキ工程において、界面活性剤やレベリング剤、光沢剤としてリン化合物を含む物質を使用すると、本実施例と同様に、その使用量および条件によりニッケル多孔体に含まれるリン元素の含有量が変化した。これらの多孔体を用いて、電池を構成し、寿命試験を行った。その結果、リン元素の含有量が多いほど寿命特性は低下した。

【0027】リン含有量が多い多孔体を用いた電池には、以下の傾向が見られた。

(1) 劣化電池は充放電をくり返すに伴い、その内部抵抗が上昇し放電電圧が低下した。

【0028】(2) 安全弁の作動等による電解液の減少は殆どない。

(3) 各電池A～Fの変更点はリン含有量のみである。

【0029】これらの点を鑑みて、寿命劣化の原因は、正極のスポンジ状ニッケル多孔体とリンが、Ni₃P等を形成し、腐食に伴う正極の導電性低下が劣化の原因であると推測できる。

【0030】したがって、ニッケル重量に対するリン含有量が0.20重量%まで増加すると、その寿命特性が極端に低下すること、およびスポンジ状ニッケル多孔体の作成工程上の観点、具体的には水洗工程の煩雑さや使用水量などの経済面から、リン含有量の許容範囲は、ニッケル多孔体重量に対し0.10重量%以下であった。

【0031】尚、本実施例では、スポンジ状ニッケル多孔体を、その基材となるスポンジ状ウレタンの表面にニッケルの化学メッキにより導電性を付与した後、ニッケルを電気メッキし、次に前記スポンジ状有機物を燃焼除去することによって得た。ニッケルの化学メッキ量を多くし、電気メッキ工程を省略しても前記多孔体を得ることができる。しかしながら、多量のニッケルの化学メッキを均一に行うには、長時間を要すること、更に多量のリンが混入するため、規定含有量以下にリン含有量を制御することが困難なこと等から、スポンジ状ニッケル多孔体は、その基材となるスポンジ状有機物多孔体表面に化学メッキにより少量のニッケル導電層を付与した後、

ニッケルを電気メッキし、前記スポンジ状有機物を燃焼除去して得る方法が望ましい。

【0032】また、リン化合物を含む化学メッキ工程を行わない場合でも、電気メッキ工程において光沢剤、界面活性剤、レベリング剤等に含まれるリン化合物の混入により、スポンジ状ニッケル多孔体中のリン含有量が0.10重量%以上となると上記同様の不具合が生じることを確認した。

【0033】以上述べたように、本発明は、正極のスポンジ状ニッケル多孔体中のニッケル重量に対するリン含有量をニッケル重量に対し0.10重量%以下に制御することにより、寿命特性に優れた電池を提供するものであり、その工業的価値は大きい。

【0034】ところで本実施例では、正極活物質の保持体である金属多孔体としてニッケル多孔体を例にとって記述した。しかし、耐アルカリ性と導電性とを兼ね備えた他の金属材料を使用しても良く、特にニッケルと同様にリンとの化合物を形成しやすい金属材料の場合において、本発明の効果は大きい。

【0035】また、金属多孔体としては、本実施例では、スポンジ状ニッケル多孔体を用いたが、例えばパンチングメタルに多孔性ニッケルを被覆したものなどでも同様の効果が得られる。

【0036】また、正極には、水酸化ニッケル粉末100重量部に対し酸化コバルト粉末を6重量部添加した場合について記述した。しかし、他の組成、例えば添加物として水酸化コバルト粉末や金属コバルト粉末、金属Ni粉末などを用いた水酸化ニッケル正極でも同様の傾向が得られる。

【0037】更に、本実施例では、ニッケル・水素蓄電池を用いたが、ニッケル・亜鉛蓄電池、二酸化マンガン・水素蓄電池など、他のアルカリ蓄電池においても同様の効果が認められることは言うまでもない。

【0038】

【発明の効果】以上のように、本発明によれば、金属酸化物を主体とする活物質を金属多孔体に保持させた正極と、負極と、アルカリ電解液と、セパレータとから成る発電要素において、前記金属多孔体に含まれるリン元素の含有量を金属多孔体重量に対し0.10重量%以下にすることにより、寿命特性に優れたアルカリ蓄電池を提供できる。

【図面の簡単な説明】

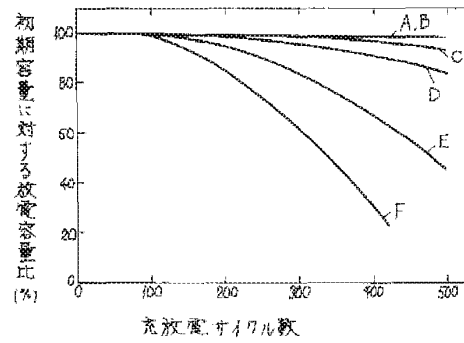
【図1】充放電サイクル数と初期容量に対する放電容量比率との関係を示す図

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【図1】

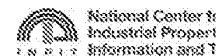


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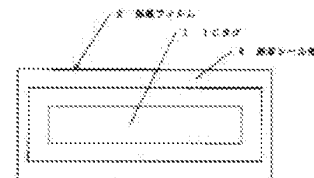
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(54)PROTECTIVE FILTER AND PROTECTION METHOD OF IC TAG

(57)Abstract

PROBLEM TO BE SOLVED: To provide a protective film which is excellent in heat resistance, water resistance and solvent resistance for the purpose of protection of an IC tag and a protection method therefor.

SOLUTION: The protective film 2 for protecting the tag for management (IC tag 1) packaged with an IC readable without contact is formed of a polyether ether ketone (PEEK), polyether sulfone (PES), polyether imide (PEI), polysulfone (PSF), polyamide (PA), polyimide (PI), polyamide amide (PAI) or polytetrafluoroethylene (PTFE) material.

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CA23

(54) 【発明の名称】 ICタグの保護フィルム及び保護方法

(57) 【要約】

【課題】 ICタグの保護のため、耐熱性、耐水性及び耐溶剤性に優れた保護フィルム及び保護方法を提供すること。

【解決方法】 非接触で読み取り可能な IC を実装した管理用タグ (ICタグ) を保護する保護フィルムであって、該保護フィルムがポリエーテルエーテルケトン (PEEK)、ポリエーテルサルフォン (PES)、ポリエーテルイミド (PEI)、ポリサルフォン (PSF)、ポリアミド (PA)、ポリイミド (PI)、ポリアミドイミド (PAI)、又はポリテトラフルオロエチレン (PTFE) 材で形成されている ICタグの保護フィルム。

(2) 開2001-66990(P2001-6)号

【特許請求の範囲】

【請求項1】 非接触で読み取り可能なICを実装した管理用タグ(ICタグ)を保護する保護フィルムであって、該保護フィルムがポリエーテルエーテルケトン(PEEK)、ポリエーテルサルフォン(PES)、ポリエーテルイミド(PEI)、ポリサルフォン(PSF)、ポリアミド(PA)、ポリイミド(PI)、ポリアミドイミド(PAI)、又はポリテトラフロエチレン(PTFE)材で形成されていることを特徴とするICタグの保護フィルム。

【請求項2】 請求項1記載の保護フィルムにより小袋を形成し、その中にICタグを挿入後、密封することを特徴とするICタグの保護方法。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、例えばクリーニングやレンタルユニフォームなどの管理を目的として使用される非接触型のICタグを保護する材料及び保護方法に関する。

【0002】

【従来の技術】近年、非接触型のICカードやICタグが普及してきており、情報や製品の個別管理に活用されている。特に非接触型のICタグは大幅なコストダウンにより広い範囲でその用途を検討されているが、クリーニングやレンタルユニフォームなどの管理を目的とした用途もその一つである。

【0003】

【従来の技術】従来のレンタルユニフォームでは、バーコードの印刷されたタグを貼り付けて使用頻度など個別の管理を行っていたが、バーコードをいちいち読み取る作業を行うことは実際には難しく、決められたクリーニング回数又は使用期間に満たないものが消却されることがあるなど、製品の管理が不安定であった。

【0004】従って上記用途に非接触型のICタグを使用することは、読み取り作業の効率も良く非常に有用である。しかしその用途上、常に衣服に貼り付いていなければならないため、クリーニングの際の熱、水、溶剤及び圧力が繰り返し加わってくることになり、ICタグが正常に作動しなくなる恐れが非常に大きかった。

【0005】ICタグの構造は、アンテナの形成されたPET等のフレキシブルな基板上にICが実装されており、接着剤を介して保護フィルムが貼り合わされているため、水や溶剤などに浸かると接着界面から浸漬して故障の原因になったり、熱が直接タグにかかるためそこでも故障の原因になっていた。

【0006】

【発明が解決しようとする課題】本発明の目的は、ICタグの保護のため、耐熱性、耐水性及び耐溶剤性に優れた保護フィルム及び保護方法を提供することにある。

【0007】

【課題を解決するための手段】本発明は、非接触で読み

取り可能なICを実装した管理用タグ(ICタグ)を保護する保護フィルムであって、該保護フィルムがポリエーテルエーテルケトン(PEEK)、ポリエーテルサルフォン(PES)、ポリエーテルイミド(PEI)、ポリサルフォン(PSF)、ポリアミド(PA)、ポリイミド(PI)、ポリアミドイミド(PAI)、又はポリテトラフロエチレン(PTFE)材で形成されているICタグの保護フィルムである。更に本発明は、上記保護フィルムにより小袋を形成し、その中にICタグを挿入後、密封するICタグの保護方法である。

【0008】

【発明の実施の形態】本発明に使用する保護フィルムとしては、熱可塑性の樹脂で耐熱性及び耐薬品性に優れた樹脂が適しており、ポリエーテルエーテルケトン(PEEK)、ポリエーテルサルフォン(PES)、ポリエーテルイミド(PEI)、ポリサルフォン(PSF)、ポリアミド(PA)、ポリイミド(PI)、ポリアミドイミド(PAI)、又はポリテトラフロエチレン(PTFE)材である。

【0009】本発明のICタグの保護方法としては、ICタグより一回り大きい上下2枚の保護フィルムを4方で熱溶着して密封しても良いし、半折した保護フィルムにICタグを挟み3方を熱溶着して密封しても良い。

【0010】本発明では、耐熱性、耐水性及び耐溶剤性に優れた熱可塑性のプラスチックフィルムを熱溶着等の方法で外装袋を予め形成し、その中へICタグを挿入後密封する事が好ましい。

【0011】上記手段により、クリーニング又はレンタルユニフォームの管理に使用するICタグを熱、水及び溶剤から守り、ICタグの長寿命化の実現を可能にすることができる。クリーニング時にかかる条件としては、洗濯時に70℃の温水に数分、乾燥時に180℃で10分、プレス時に200℃で5〜10分程度が考えられる。

【0013】又、クリーニング時の溶剤としては、塩素系、フロン系等のが挙げられるが、本発明の保護フィルムによりICタグが直接溶剤に触れることを防ぐ。

【0014】

【実施例】以下に本発明の実施例について図面を参照しながら説明する。本発明は実施例により、特に限定されるものではない。図1は本発明の第1の実施例における非接触型ICタグの保護形態である。ICタグ1は保護フィルム2を熱溶着シールにより溶着シール部3を形成することにより密封包装されており、外部からの水や溶剤などがICタグに直接触れないように保護している。保護フィルム2としては、熱可塑性の樹脂で耐熱性及び耐薬品性に優れたポリエーテルエーテルケトン(PEEK)を使用する。包装方法としては、ICタグより一回り大きい上下2枚の保護フィルムを4方で熱溶着して密封する。

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【0015】図2は本発明の第2の実施例における非接触型ICタグの保護形態である。ICタグ1は保護フィルム2を熱溶着シールにより溶着シール部3を形成することにより密封包装されており、外部からの水や溶剤などがICタグに直接触れないように保護している。保護フィルム2としては、熱可塑性の樹脂で耐熱性及び耐薬品性に優れたポリエーテルエーテルケトン(PEEK)を使用する。包装方法としては、ICタグより一回り大きい半折した保護フィルムにICタグを挟み3方を熱溶着して密封する。

【0016】

【発明の効果】本発明によれば、ICタグを熱可塑性の

樹脂で耐熱性及び耐薬品性に優れたプラスチックフィルムで密封することにより、ICタグをクリーニング時の水や溶剤から保護し、熱伝導も緩和させることで、ICタグの長寿命化を達成させたため、ICタグの信頼性が向上する。

【図面の簡単な説明】

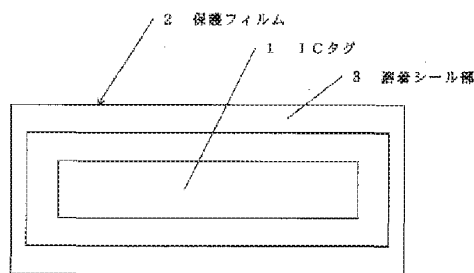
【図1】 本発明のICタグの保護形態の第1の実施例

【図2】 本発明のICタグの保護形態の第2の実施例

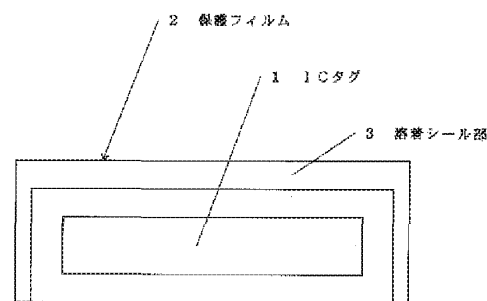
【符号の説明】

- 1 非接触型ICタグ
- 2 保護フィルム
- 3 溶着シール部

【図1】



【図2】

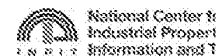


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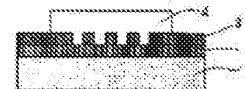
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JP,05-325705,A

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(11)Publication number	05-325705
(43)Date of publication of application	10.12.1993
(51)Int.Cl.	H01H 13/02
	H01H 13/70
(21)Application number	04-158843
(22)Date of filing	27.05.1992
(71)Applicant	FUJI PORIMATETSUKU KK
(72)Inventor	SASAKI YASUSHI



(54)ILLUMINATION TYPE CONTACT SHEET

(57)Abstract

PURPOSE: To simplify manufacture and realize thinning by incorporating an EL sheet as it is as a contact sheet, and printing a character part on its upper surface.

CONSTITUTION: A color ink 2 is applied to an EL sheet 1 having elasticity. Character engraving printing is applied by means of screen-printing with a polyester black ink 3 thereon.

Subsequently, a key-top part 4 is formed thereon with a transparent resin to produce an illumination type contact sheet. Here, application of the color ink 2 can be omitted when a colored EL sheet is used. Accordingly, a thin illumination type contact sheet can be produced in less manufacturing processes, so that manufacturing can be simplified resulting in cost reduction.

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(19)日本国特許庁(JP)

(12) 公開特許公報(A)

(11)特許出願公開番号

特開平5-325705

(43)公開日 平成5年(1993)12月10日

(51)Int.Cl. ⁵	識別記号	庁内整理番号	F I	技術表示箇所
H 0 1 H 13/02	A	7250-5 G		
13/70	D	7373-5 G		

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(22)出願日 平成4年(1992)5月27日

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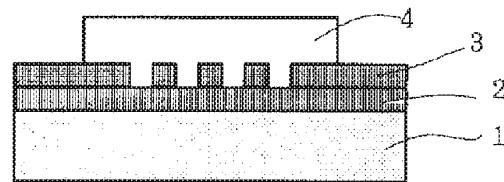
(74)代理人 弁理士 松田 省躬

(54)【発明の名称】 照光式接点シート

(57)【要約】

【目的】 照光式接点シートの薄型化、および製造工程の省略を図る。

【構成】 ELシートをそのまま接点シートとして使用する。



(2)

特開平5-325705

【特許請求の範囲】

【請求項1】 弾性を有するELシート上に、遮光性塗料を文字抜き印刷し、さらにその表面に透明樹脂のキートップ部が形成された照光式接点シート。

【請求項2】 ELシートの上面が色インキ塗装されている請求項1記載の照光式接点シート。

【発明の詳細な説明】

【0001】

【産業上の利用分野】本発明は、電子機器のスイッチ部に使用する照光式接点シートに関するものである。

【0002】

【従来の技術】従来の照光式接点シートは、LEDあるいはELにより裏側から文字部を照光している。

【0003】

【発明が解決しようとする課題】従来の照光式接点シートは、この接点シートの裏側に発光装置を配置する必要があり、製造工程が増すばかりでなく、そのための空間が必要となるため、薄型化が図れない欠点を有する。

【0004】

【課題を解決するための手段】そこで本発明にあっては、ELシートをそのまま接点シートとして組み込み、この上面に文字部を印刷するようにした。これにより製造が簡単となり、かつ薄型化が図れるようにしたもので

ある。

【0005】

【実施例】図1に実施例を断面図で示す。

【0006】弾性を有するELシート1上に、色インキ2を塗布し、その上にポリエステル系黒インキ3（セイコーアドバンس：RUX）にて、スクリーン印刷により文字抜き印刷し、その上に透明樹脂（スリーボンド：TB3003）にてキートップ部4を形成して照光式接点シートを作製した。なお、色付きELシートを使用することで、色インキ2の塗布を省略できる。

【0007】

【発明の効果】本発明によれば、薄型の照光式接点シートを少ない製造工程で製作できるので、製造が簡単であり、コストも低減できる。また、ELシートの色を文字部の色として直接利用することで、色インキの塗装工程も省略でき、より製造コストを低減できる。

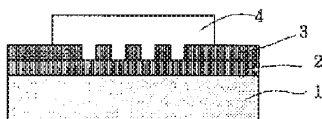
【図面の簡単な説明】

【図1】実施例の断面図

【符号の説明】

- 1 ELシート
- 2 色インキ
- 3 黒インキ
- 4 透明樹脂

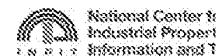
【図1】





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G01N 21/35

(21)Application number 2000-259292
(22)Date of filing 29.08.2000
(71)Applicant CAS MEDICAL SYSTEMS INC
(72)Inventor BENNI PAUL

(30)Priority

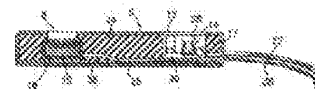
Priority number : 1999 151319 Priority date : 30.08.1999 Priority country : US
1999 434142 04.11.1999 US

(54)NEAR INFRARED RADIATION SPECTROPHOTOMETRIC INSPECTION DEVICE

(57)Abstract

PROBLEM TO BE SOLVED: To provide a reusable transducer device for a near infrared radiation spectrophotometric inspection capable of accurately controlling a laser beam irradiated to the skin of a patient.

SOLUTION: A transducer device 2 for a near infrared radiation spectrophotometric inspection for inspecting oxygen in blood of the body of a patient without injuring a tissue has a housing 4 directly stickable to the skin S of the patient. The inside of the housing includes plural laser diodes 14 capable of emitting near infrared radiation having different wave lengths and a photodiode assembly 18 for detecting intensity of the light passing through the body of the patient by being radiated from the laser diodes. A light guide 28 is arranged on the laser diodes to directly contact with the skin of the patient to attenuate a laser beam irradiated to the skin to a safe irradiation level. The transducer device can be reused by housing the housing 4 in a disposable adhesive envelope 42 or a pad 54.



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C 0 1 N 21/35

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G 0 1 N 21/35

A 6 1 B 5/14

3 1 0

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(33) 優先権主張国 米国 (U S)

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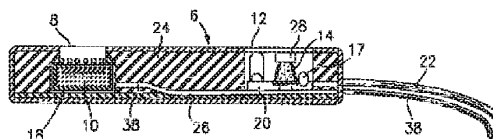
弁理士 浅村 皓 (外3名)

(54) 【発明の名称】 近赤外線分光測光検査装置

(57) 【要約】

【課題】 患者の皮膚に照射されるレーザー光を正確に制御することができ、再使用可能な近赤外線分光測光検査用トランスジューサ装置を実現する。

【解決手段】 組織を冒さずに患者の体の血液中酸素を検査するための近赤外線分光測光検査用トランスジューサ装置2は、患者の皮膚Sに直接貼り付けることができるハウジング4を有する。ハウジング内に、異なる波長の近赤外光を発光することができる複数のレーザーダイオード14と、レーザーダイオードから放射されて患者の体を通った光の強度を検出するフォトダイオード・アセンブリ18を含む。光ガイド28がレーザーダイオードの上に設けられ、直接患者の皮膚と接触し、皮膚に照射するレーザー光を安全な照射レベルに減衰させる。使い捨ての粘着性封筒42、またはパッド54内にハウジングを収容することにより、トランスジューサ装置を再使用することができる。



(2) 開2001-87250 (P2001-87250A)

【特許請求の範囲】

【請求項1】 組織を冒さずに患者の体の血液中の酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

- a) 患者の体に直接貼り付けることができる少なくとも1個の柔軟なハウジングと、
- b) 該ハウジング内に配置され、各々が異なる波長の近赤外光信号を放射することができる複数のレーザーダイオードと、
- c) 患者の体に直接貼り付けることができ、該レーザーダイオードから放射されて患者の体を通った光の強度を測定することができるように、該レーザーダイオードと機能的に結合しているフォトダイオード・アセンブリとを含む、近赤外線分光測光(NIRS)検査装置。

【請求項2】 請求項1記載の装置において、前記フォトダイオード・アセンブリが前記ハウジング内に配置されている、NIRS検査装置。

【請求項3】 請求項1記載の装置において、前記ハウジング内に配置され、前記フォトダイオード・アセンブリにより常に検出することができる光を発する補助発光器を更に含み、それによって、該補助発光器から発して検出された光の強度が増減してあらかじめ定められた範囲外になったとき、前記NIRS検査装置が患者の皮膚から外れたことを前記フォトダイオード・アセンブリとNIRSシステムプロセッサに示す、NIRS検査装置。

【請求項4】 請求項1記載の装置において、前記フォトダイオード・アセンブリは周囲の電磁干渉から遮蔽されている、NIRS検査装置。

【請求項5】 請求項1記載の装置において、前記フォトダイオード・アセンブリは第2のハウジング内に収容されている、NIRS検査装置。

【請求項6】 請求項1記載の装置において、前記レーザーダイオードの上に堅い光ガイドが設けてあって、該光ガイドは前記NIRS検査装置が患者に貼り付けられているとき直接患者の皮膚と接触するように前記ハウジング内に配置されている、NIRS検査装置。

【請求項7】 請求項6記載の装置において、前記光ガイドは前記NIRS検査装置が患者に取り付けられているとき患者の皮膚と接触する平坦な表面を有する、NIRS検査装置。

【請求項8】 請求項1記載の装置において、前記ハウジングと患者の皮膚との間にあって前記NIRS検査装置を患者の皮膚に粘付着する使い捨ての殺菌した粘着性封筒またはパッドを更に含む、NIRS検査装置。

【請求項9】 組織を冒さずに患者の体の血液中酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

- a) 患者の体に直接貼り付けることができる少なくとも1個の柔軟なハウジングと、
- b) 該ハウジングと機能的に結合し、各々が異なる波長の

近赤外光信号を放射することができる複数のレーザーダイオードと、

c) 患者の体に直接貼り付けることができ、該レーザーダイオードと機能的に結合して、該レーザーダイオードから放射されて患者の体を通った光の強度を測定することができるフォトダイオード・アセンブリと

d) 該ハウジング内に配置され、該フォトダイオード・アセンブリにより常に検出することができる光を発することができる補助発光器であって、それによって、該補助発光器から発して検出された光の強度が増減してあらかじめ定められた範囲外になったとき、該NIRS検査装置が患者の皮膚から外れたことを該フォトダイオード・アセンブリとNIRSシステムプロセッサとに示す、補助発光器と、を含む、近赤外線分光測光(NIRS)検査装置。

【請求項10】 請求項9記載の装置において、前記補助発光器は発光ダイオードである、NIRS検査装置。

【請求項11】 請求項9記載の装置において、前記レーザーダイオードは前記ハウジング内に収容されている、NIRS検査装置。

【請求項12】 請求項11記載の装置において、前記レーザーダイオードの上に堅い光ガイドが設けてあって、該光ガイドは前記NIRS検査装置が患者に貼り付けられているとき直接患者の皮膚と接触するように前記ハウジング内に配置されている、NIRS検査装置。

【請求項13】 請求項12記載の装置において、前記光ガイドは前記NIRS検査装置が患者に貼り付けられているとき患者の皮膚と接触する平坦な表面を有する、NIRS検査装置。

【請求項14】 組織を冒さずに患者の体の血液中酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

a) 患者の体に直接貼り付けることができる少なくとも1個の柔軟なハウジングと、

b) 該ハウジング内に配置され、各々が異なる波長の近赤外光信号を放射することができる複数の光源と、

c) 患者の体に貼り付けることができ、該光源から放射されて患者の体を通った光の強度を測定することができるように、該光源と機能的に結合しているフォトダイオード・アセンブリと、

d) 該ハウジングと患者の皮膚との間にあって、該NIRS検査装置を患者の皮膚に粘付着する使い捨ての殺菌した粘着性封筒または粘着性パッドとを含む、近赤外線分光測光(NIRS)検査装置。

【請求項15】 組織を冒さずに患者の体の血液中酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

a) 患者の体に直接貼り付けることができる少なくとも1個の柔軟なハウジングと、

b) 該ハウジング内に配置され、各々が異なる波長の近赤外光信号を放射することができる複数の光源と、

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c) 患者の体に直接貼り付けることができ、該レーザダイオードと機能的に結合して、該光源から放射されて患者の体を通った光の強度を測定することができるフォトダイオード・アセンブリと、

d) 該フォトダイオード・アセンブリを囲む周囲の電磁干渉(EMI)シールドであって、該EMIは、該フォトダイオード・アセンブリと、該NIRS検査装置が患者の体に貼り付けられているとき患者の皮膚に接するNIRS検査装置の表面との間に挿入されている導電性網スクリーンと、該フォトダイオード・アセンブリの全表面のうち該網スクリーンによりおおわれていないすべての表面をおおう導電性カプセルとを含み、該網スクリーンと該導電性カプセルとにより周囲のEMIが該NIRS検査装置の動作に影響するのを防止しながら、該発光源から放射される光の強度の測定を可能にする、EMIシールドとを含む、近赤外線分光測光(NIRS)検査装置。

【請求項16】 組織を冒さずに患者の体の血液中酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

a) 患者の体に直接貼り付けることができる少なくとも1個の柔軟なハウジングと、

b) 該ハウジング内に配置され、各々が異なる波長の近赤外光信号を放射することができる複数のレーザダイオードであって、該レーザダイオードの上に堅い光ガイドが設けてあって、該光ガイドは該NIRS検査装置が患者に貼り付けられているとき直接患者の皮膚と接触するように該ハウジング内に配置されている、レーザダイオードと、

c) 患者の体に直接貼り付けることができ、該レーザダイオードと機能的に結合して、該レーザダイオードから放射されて患者の体を通った光の強度を測定することができるフォトダイオード・アセンブリとを含む、近赤外線分光測光(NIRS)検査装置。

【請求項17】 組織を冒さずに患者の体の血液中酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

a) 患者の体に直接貼り付けることができ、透明な窓を有する少なくとも1個の柔軟なハウジングと、

b) 該ハウジングと機能的に結合して、各々が異なる波長の近赤外光信号を放射することができ、該光信号が該ハウジングの窓を通して伝達されるようになっている複数の光源と、

c) 患者の体に直接貼り付けることができ、該光源から放射されて患者の体を通った後の光の強度信号を測定することができるフォトダイオード・アセンブリと

d) 該光源の減衰を制御し、該フォトダイオード・アセンブリから供給される光の強度信号を処理するプロセッサと、

e) 該プロセッサと該光源と該フォトダイオード・アセンブリとの間に挿入されたコネクタハウジング・アセンブリであって、該コネクタハウジング・アセンブリは該プロセッサと該光源とに接続された光源電力制御ドライバと、該プロセッサに必須のNIRS動作校正情報を供給するために該プロセッサに接続された符号化校正機構とを含む、コネクタハウジング・アセンブリとを含む、近赤外線分光測光(NIRS)検査装置。

【請求項18】 請求項17記載の装置において、前記プロセッサと前記フォトダイオードとの間に挿入されたフォトダイオード前置増幅器を更に含む、NIRS検査装置。

【請求項19】 請求項17記載の装置において、前記光源電力制御ドライバは調整可能である、NIRS検査装置。

【請求項20】 組織を冒さずに患者の体の血液中酸素レベルを検査するための近赤外線分光測光(NIRS)検査装置であって、該装置は

a) 患者の体に直接貼り付けることができる少なくとも1個の柔軟なハウジングと、

b) 該ハウジング内に配置され、各々が異なる波長の近赤外光信号を放射することができる複数のレーザダイオードと、

c) 患者の体に直接貼り付けることができ、該レーザダイオードと機能的に結合して、該レーザダイオードから放射されて患者の体を通った光の強度を測定することができるフォトダイオード・アセンブリと

d) 該光源の減衰を制御し、該フォトダイオード・アセンブリから供給される光の強度信号を処理するプロセッサと、

e) 該レーザダイオードに近接して配置されたサーミスタであって、該サーミスタは該プロセッサに機能的に接続して、該レーザダイオードの波長と電力の変動を補償するために、該レーザダイオードの温度を監視してレーザダイオードの動作温度情報を該プロセッサに供給する、サーミスタとを含む、近赤外線分光測光(NIRS)検査装置。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は組織を冒さない近赤外線分光測光(NIRS)光トランスジューサ装置に関するものである。本発明は特に、再使用することができ、患者の皮膚に正確なサイズの減衰したレーザ光を供給することができるNIRS光トランスジューサ装置に関するものである。

【0002】

【従来の技術】近赤外線分光測光(NIRS)は組織中の酸素を絶えず監視する光学的分光測光法である。NIRS法は、近赤外線範囲(700~900nm)の光は容易に皮膚、骨およびその他の組織を通過するが、これらの波長範囲内ではヘモグロビンがその酸素の状態、すなわち酸化ヘモグロビン(HbO₂)と非酸化ヘモグロビン(Hb)、に依存する特定の吸収スペクトルを有するという原理に基づいている。複数の特定の波長を有する近赤外光を発する光源を使っ

(4) 開2001-87250 (P2001-87250A)

て、伝達または反射した光の減衰の変化を測ることによって、HbO₂とHbの酸素濃度の変化を監視することができる。

【0003】ヘモグロビン総量はヘモグロビンの二つの状態の和であり(Total Hb= HbO₂+Hb)、もしヘマトクリット値または血液中のヘモグロビン濃度が不変であれば、相対的な血液量の変化に比例する。NIRSの最も価値ある点は、特に病気のとき、大人または新生児の脳の酸素レベルを常に監視することができることである。この場合、脳の酸素レベル次第では脳が損傷するか、あるいは死に至る可能性がある。

【0004】近赤外光は新生児の皮膚と頭蓋を容易に通過し、脳のある生体分子により吸収されることが知られている。近赤外線分光測光(NIRS)は、近赤外線スペクトル(700~900nm)において発色団の酸化ヘモグロビン(HbO₂)と非酸化ヘモグロビン(Hb)とが異なる吸収特性を有することに基づいて、主に微細な循環レベル(毛細管、細動脈および小脈)で、生体組織(脳、筋肉、またはその他の器官)における酸素の変化を検出する。サブ秒の時間分解能を用いたとき、平均的な組織への侵入は2-3cmである。HbO₂とHbとの濃度の相対的变化はモデファイド・ピア・ランバートの法則を使って定量化することができる。この法則は生物組織のような散乱の大きい媒体における光の減衰を考慮に入れている。モデファイド・ピア・ランバートの法則は次の数式で表すことができる。

【0005】

【数1】

$$A = -\log(I_0/I) = a_L \times C \times d \times B + G$$

【0006】ここでAは波長Lにおける組織内の光減衰であり(単位は光学濃度=OD)、I₀は入射光の強度(単位はW/cm²)、Iは検出した光の強度、a_Lは発色団の波長依存性吸収係数(単位はOD×cm⁻¹×μM⁻¹)、Cは発色団の濃度(単位はμM)、dは光源と検出器との距離(単位はcm)、Bは光散乱経路長差係数(単位はない)、Gは組織の形と光の散乱に関する因子(単位はOD)である。

【0007】発色団の濃度の絶対的な測定はGが未知であるから非常に難しい。しかし、数時間から数日間という妥当な測定期間中、Gは一定であるから、発色団のゼロ基準線からの相対的变化を測ることができる。したがって、もし時間t₁において光学的測定(基準線)を開始した後、時間t₂が任意の時間であれば、変数GとI₀とが一定ならばそれらを消去して、差減衰ΔAを計算することができる。目的は次の数式から導かれるΔAを使って発色団濃度の変化[ΔC=C(t₂)-C(t₁)]を決定することである。

【0008】

【数2】

$$\Delta A = -\log(I_2/I_1) = a_L \times \Delta C \times d \times B$$

【0009】発色団の1より大きい相対的变化を計算す

るように意図されたNIRSアルゴリズムは数式2の多変数形式を用いる。酸化ヘモグロビン(HbO₂)と非酸化ヘモグロビン(Hb)の相対的变化を区別して計算するために、最低2個の異なる波長を用いることが好ましく、レーザダイオードのようなスペクトル帯域幅の狭い光源を用いるのが好ましい。ΔHbO₂とΔHbの単位は組織1リットルあたりのマイクロモル(μM)であり、これは数式1の大きさの分析から決められる。

【0010】米国特許第5,217,013号、第5,465,714号、第5,482,034号、第5,584,296号ではそれらのNIRSシステムの柔軟な粘着性表面を実装可能なハウジングの中に、NIRS光源としての発光ダイオード(LED)と2個のフォトダイオードとを用いている。NIRS測定器の光源としてLEDを用いるときの問題は、LEDのスペクトル帯域幅がレーザダイオードのそれ(<1nm)よりずっと広い(20-50nm)ことである。組織を冒さないNIRSアルゴリズムの開発で使うには、スペクトル帯域幅の狭い光源の方がはるかに使いやすく、それによって生体パラメータのより高信頼性かつ高精度の計算に導くことが可能になる。したがって、低電力でスペクトル帯域幅の狭い光源を複数個直接NIRSプローブハウジングに組み込んで使うことは、NIRSプローブに帯域幅の広いLED光源を使うのに比べて改良となる。

【0011】米国特許第5,465,714号と第5,584,296号に開示されているような堅い環状光ガイドは、内部が外気に向けて開放されたくほみを有する構造になっていて、これは光減衰能力を持たない。これらの環状光ガイドの壁は光学部品から発する光を反射して返す。この構造はNIRSシステムにとって望ましくない。なぜならば、外気に向けて開放されたくほみを有する環状ハウジングを皮膚に押しつけたとき、皮膚が変形するので、もし光の測定期間中皮膚の変形を予想するかまたは一定に維持するための機構が何もなければ、皮膚に当たる光の強度があらかじめ決められないからである。

【0012】従来技術のNIRSハウジングの実装システムは1個の部品のシステムであり、そこでは患者の皮膚と接するプローブハウジングの表面が1回使いの粘着性を有するので、これらのプローブは1回使用に設計されていて、使用後捨てられる。このやり方はコストがかかり、浪費的である。

【0013】米国特許第4,321,930号、第4,380,240号、第4,510,938号、第5,353,791号では、光ファイバーによりレーザ光源と接続された光トランスジューサが開示されている。米国特許第5,353,791号にはまた、レーザ光ガイドとして働く透明なスペーサが述べられている。透明なスペーサには好ましくは弾力性の手段が備わっている。これらの特許には患者の皮膚に照射されるレーザ光のレベルを意図的に下げるための特別な光強度減衰構造が開示されていない。

【0014】

(5) 開2001-87250 (P2001-87250A)

【発明が解決しようとする課題】レーザダイオードを内蔵し、NIRS光トランスジューサ装置を使用中に患者の皮膚に照射されるレーザ光のエネルギーレベルとサイズとを正確に制御することができ、再使用可能なNIRS光トランスジューサ装置を実現することが望ましい。

【0015】

【課題を解決するための手段】本発明は人間の患者の近赤外線分光測光(NIRS)に使用するための改良された光トランスジューサ装置に関するものである。異なる波長で発光する2個以上のレーザダイオードと1個以上のフォトダイオードとが1個の柔軟なハウジングの中に収容されていて、ハウジングは患者の頭または体のその他の部分に容易にしっかりと貼り付けることができる。レーザダイオードから皮膚に照射されるレーザ光の強度を減らす目的で、堅い光ガイドがレーザダイオードと患者の皮膚との間に配置されているので、人体組織に対するレーザ照射に関するアメリカ国立標準協会により発行されているレーザ安全基準を満たす。堅い光ガイドはまた電力範囲が5〜40mWの中で入手可能なレーザダイオードを広く選択して使用することができるように、光減衰能力も持たせることができる。したがって、所望の波長とパッケージサイズを有するが出力電力の点で利用できないレーザダイオードが、NIRSプローブ光トランスジューサに適当な光ガイドを付すことで利用することができる。堅い光ガイドの光減衰性のおかげで、5〜40mWの電力範囲にあるクラス3のレーザダイオードを組み込んでクラス1のレーザ製品を設計することが可能になる。クラス1のレーザ製品に分類されることは重要である。なぜならば規制と安全に対する基準がクラス1の装置では厳しさがずっと少ないからである。堅い光ガイドはまたレーザダイオード発光器と皮膚間の距離を一定に保つことによって、測定中に要求される分光測光測定システムの一定の光強度出力を満す。

【0016】本発明のNIRS光トランスジューサ装置は、2個の分離可能な部品、NIRSプローブハウジングと使い捨ての粘着性封筒またはパッドから構成することができる。NIRSプローブハウジングは上述のようにレーザダイオードとフォトダイオードとを含み、使い捨ての粘着性封筒またはパッドはNIRS光トランスジューサ装置のハウジングを患者の皮膚に容易にしっかりと貼り付けるのに使う。使い捨てのNIRS光トランスジューサ・ハウジングよりも使い捨て封筒付きの使い捨てでないNIRS光トランスジューサ・ハウジングを使う方が、経済的に望ましい。また、特に公衆衛生と殺菌状態が最高である健康管理環境において、1個使いの使い捨て光トランスジューサの応用という利点をすべて維持している。

【0017】従来のレーザダイオードと光ファイバとを結合したNIRSヘッドバンド・トランスジューサ・システムの場合、狭いスペクトル帯域幅(<1-3nm)を有する光放射を使う利点が維持されている。本発明のトランスジューサ装置に低電力のレーザダイオードを使うことによ

り、従来の光ファイバ部品のコストを除くと共に、NIRS光トランスジューサ装置の製造コストを軽減する。従来の光ファイバ部品はまた脆くて壊れやすい。

【0018】本発明のトランスジューサ装置におけるより低電力のレーザダイオードは、自己加熱が起きないように、低いデューティサイクルでパルス発光させることができる。それによって、レーザダイオードの金属ケースの肌触りを涼しく維持すると共に、温度に起因する波長の変動を最小限にしている。従来技術のより高電力のレーザダイオード／光ファイバNIRS光トランスジューサ・システムは温度制御システムと自己発生した熱を放散するためのヒートシンクとを必要としている。自己加熱が無視できれば、本発明のNIRS光トランスジューサ装置で使われている低電力のレーザダイオードは、ガラスまたは透明なプラスチック材料のような光の伝達性がよく電気的に絶縁性の薄くて堅い光ガイド材料により、患者の皮膚に近接させることができる。サーミスタをレーザダイオードの隣に置いて、温度情報をNIRSシステムプロセッサに供給することにより、電力と波長の変動を補償することができる。

【0019】レーザダイオードの出力窓の上に設けたレーザダイオードの光ガイドはいくつかの機能を有する。ひとつの機能はレーザダイオードの長円形円錐形の放射特性を利用することによって、分光測光監視下の患者の皮膚に当たるレーザ光の強さを弱めることである。すなわち、レーザダイオード発光器のチップと皮膚の表面間の分離距離(r)を大きくすれば、レーザ光の強度(面積あたりの電力)は r^2 の率で減る。人間の額または人間の体のその他の部分に直接当たるようにレーザダイオード方式の光トランスジューサ装置を設計する上で、このことは重要なことである。皮膚と組織の安全を確保するために、レーザダイオード式光トランスジューサ装置は、レーザを安全に使用するためのアメリカ国家標準(ANSI Z39.1-1993)により発行されている「許容可能な最大照射(MPE)」値として課された制限内で動作するように設計しなければならない。後述するように、距離 r はトランスジューサ・ハウジング内に適当なプリズムを置くことにより調節することができる。

【0020】1個以上のフォトダイオードもNIRS光トランスジューサ・ハウジング内に組み込まれている。検査する対象の大きさにより、フォトダイオードはレーザダイオードから約10mm〜約60mm以上離してある。典型的な大人の頭の場合、NIRS光トランスジューサ装置の反射モードを使うと、適切に脳の血液中酸素を検査するのに少なくとも約45mm〜約50mm離すのが望ましいと思われる。患者の種々の深さの血液中酸素を検査するために、複数のフォトダイオードを使うことができる。あるいは、検出した信号のうち頭皮の成分を補償するアルゴリズム用の基準検出器として、複数のフォトダイオードを使うことが

(6) 開2001-87250 (P2001-87250A)

できる。新生児用の場合、反射モードで検査するとき、レーザダイオードとフォトダイオードとの分離距離は約20mmという短めにして使うことができる。あるいは、頭蓋透過モードのNIRSトランスジューサ装置で検査するときには、60mmよりも離して使うことができる。レーザダイオードとフォトダイオード間の分離距離が大きいとき、表面積のより大きいフォトダイオードを使って、分離距離が大きいために、または光源の電力が低いために低下した検出光のレベルを補償することができる。

【0021】フォトダイオードの隣に、または別の装置として遠く離して、フォトダイオードの前増幅器を設けることにより、レベルの低い検出光信号を増幅することができ、増幅された信号はNIRSシステムプロセッサに供給される。

【0022】レーザダイオードに近接して配置される安全発光ダイオード(LED)はレーザ安全連動システムの一部として働き、NIRSシステムを使う人にレーザ光が照射される可能性を更に減らしている。レーザ安全連動システムの目的は、NIRSプローブが患者にしっかりと貼り付けられていない場合に、レーザダイオードのパルス発光を禁止することである。レーザダイオードのパルス発光が開始する前に、LED(波長680-980nm)が動作する。NIRSプローブが安全に取り付けられていることを検出するために、LED光のレベルがフォトダイオードにより監視される。周囲光の監視回路も決定を助けるであろう。監視活動の開始期間中、レーザ安全連動システムがプローブの安全な取り付けを示すまで、レーザダイオードはパルス発光しない。偶然にプローブが外れたら、自動的にレーザダイオードが遮断される。プローブが外れたことが示されたときは、使用者の介入を必要とするであろう。使用者がプローブを再び取り付けてレーザ安全連動システムをリセットしてから、レーザダイオードのパルス発光を再開することができる。

【0023】さもなくばフォトダイオードに伝達される周囲の電磁干渉(EMI)ノイズを減衰させるために、部分的に光学的に透明で導電性のシールドを用いてフォトダイオードを囲むことができる。シールド内に窓が設けてあって、レーザダイオードから発して検出される光がフォトダイオードの感光面に当たるようにしてある。光学的に透明で導電性のシールドは薄い金属の針金網スクリーン、導電性の透明被覆、または同様なものを含むことができる。

【0024】それ自体にレーザダイオードとフォトダイオードとを含むNIRSトランスジューサ装置ハウジングを患者の皮膚に取り付ける目的で、使い捨ての粘着性封筒またはパッドを使うことにより、トランスジューサ装置ハウジングを別の患者に再使用することができる。使い捨ての粘着性封筒、またはパッドはあらかじめ殺菌することができ、それによって患者を更に保護する。NIRSプローブ・ハウジングの表面を汚さないように維持するこ

とができるので、使い捨ての粘着性封筒、またはパッドは、患者からもらう余分な物からもNIRSトランスジューサ装置を保護する。こうして一層安全かつ容易に再使用することができる。

【0025】コネクタハウジング内に個別用のレーザダイオード・ドライバと符号化校正パラメータとを組み入れることにより、種々のNIRSトランスジューサ装置が種々のNIRSシステムプロセッサ/モニタと相互交換可能なように設計される。コネクタハウジングはシールドされた多心ケーブルにより、トランスジューサ・ハウジングの電気光学部品と結合している。NIRSシステムプロセッサはコネクタハウジング用のインターフェイス・ポートを有する。コネクタハウジングは個別用のレーザダイオード自動電力制御(APC)ドライバを含むことができ、これらは前もって決めたレーザダイオードの電力を出力するように、個別に調整される。コネクタハウジング内に符号化校正パラメータを設けることにより、NIRSシステムプロセッサはNIRSアルゴリズムを校正する複合化機構により、各々個別のNIRSの特性を決めて、種々のトランスジューサ装置に対して正確な計算を行うことができる。個別用のフォトダイオード前増幅器もコネクタハウジング内に収容することができるので、フォトダイオードの選択に柔軟性が得られる。

【0026】

【発明の実施の形態】以下、図面を参照して本発明について詳細に説明することにより、本発明を更に明らかにする。図を参照すると、図1と図2に参照番号2を付した反射型NIRSトランスジューサ装置の一実施例を示す。トランスジューサ装置2はトランスジューサ装置2の電子部品を収納したハウジング4を含む。ハウジング4は第1の窓8を有する柔軟な遮光壁6を含む。第1の窓8はハウジング4内に収納されているEMIシールドされたフォトダイオード・アセンブリ18の上にある。遮光壁6はまた第2の窓12を含み、この窓は皮膚照射用レーザダイオード・クラスタ14と安全LED16の上にある。レーザダイオード・クラスタ14、安全LED16およびサーミスタ17は印刷回路基板20上に実装されていて、印刷回路基板20は多心シールドケーブル22と接続されている。サーミスタ17はレーザダイオードの温度を監視して、NIRSアルゴリズムにより電力と波長の変動を補償することができる。ハウジング4はまた柔軟な電氣的かつ光学的に絶縁性のボディ24と柔軟な支持構造26とを含む。ボディ24はゴムまたは何らかのそのほかの適当なエラストマから作ることができる。支持構造26の上にレーザダイオード・クラスタの印刷回路基板20とEMIシールドされたフォトダイオード・アセンブリ18が実装されている。もう1本のシールドケーブル38がインターフェイスコネクタ・ハウジングを経由してフォトダイオード・アセンブリ18とNIRSシステムプロセッサ・アセンブリとを相互接続する(図12参照)。NIRSシステムプロセッサはフォトダイオ

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ード10により集められたNIRS反射率データの結果を分析する。

【0027】図3を参照すると、安全LED16とレーザダイオード・クラスタ14の実装状態の詳細が示してある。レーザダイオード・クラスタ14は堅い光ガイド28に接続され、光ガイド28はレーザダイオード・クラスタ14と患者の皮膚Sとの間に表面同士の接触を形成する。光ガイド28は堅いので、血液中酸素を監視中に患者の皮膚に押しつけると、皮膚の表面Sが平らになり、レーザダイオード・クラスタ14と皮膚の表面S間の距離が皮膚の照射面積全体にわたり均一になる。LED16は約600～約980nmの波長範囲の赤外光ビームを放射する。反射したLED赤外光の強度はレーザダイオード・クラスタ14から反射した光と一緒にフォトダイオード10により検出される。検出されたLED光の強度はトランスジューサ装置2と患者の皮膚Sとの境界の状態を監視するのに使われる。検出されたLED光の強度が弱くなった場合には、システムコントローラはトランスジューサ装置2が患者の皮膚Sから離れたとみなす。この假定がなされると、システムコントローラはレーザダイオード・クラスタ14をオフにして、付添人がトランスジューサ装置2の状態を確かめることができるように警報音を発する。

【0028】使用するレーザの強度は目の照射事故防止のためにANSI Z136.1-1993に示されている閾値よりずっと低い。これはレーザ光が円錐形の放射パターンを有し、デューティサイクルが低くかつ電力レベルが低いからである。レーザ安全連動システムを併用することにより、NIRSシステムを使った場合の人へのレーザ光照射の可能性を更に小さくする。もしNIRSアセンブリが患者にしっかりと貼り付いていなければ、レーザ安全連動システムがレーザダイオードのパルス発光を直ちに止める。レーザダイオード安全回路(LSC)はNIRSアセンブリ上でレーザダイオード14(またはそのほかのレーザ光源)の近くに配置した発光ダイオード16(LED, 600-980nm)を含む。フォトダイオード10により検出されたLED光のレベルは、特に周囲光が低い場合に、NIRSアセンブリの取り付けが安全であることを検出するのに使われる。LED16は多重化レーザダイオードパルス発光機構の中に含まれていて、NIRSアセンブリがシステムモニタに接続されているときに始終LED16が発光している場合を除き、検出された光はレーザ光と同様に処理される。ウィンドウ比較器プロセッサは、検出されたLED光がアセンブリの取り付けが安全であることを示すあらかじめ定められた範囲内にある可否かを判断する。LED光の検出レベルが低ければ、レーザ光が自由空間で放射しているかまたはさえざられている可能性があることを示すであろう。LED光の検出レベルが強ければ、生物組織を通過せずに皮膚または対象物からフォトダイオード10へ光が反射していると仮定することにより、アセンブリが外れていることを示すであろう。

【0029】通常の昼間の周囲光の場合には、検出光の直流レベルを監視することによって、更にレーザ安全連動システムが併用される。このことは、フォトダイオードの前置増幅器の出力に低域フィルタを加えることによりが実現される。検出された周囲光が、NIRSアセンブリが外れたことを示すあらかじめ定められたレベルに達すると、レーザ動作が禁止される。監視期間の始まりの間、LSCがアセンブリの取り付けが安全であることを示すまで、レーザダイオード14はパルス発光しない。偶然アセンブリが外れた場合には、レーザダイオード14は自動的に発光を停止するであろう。アセンブリが外れたことを示す場合はいつでも、レーザのパルス発光を再開することができる前に、使用者の介入を必要とする。使用者はアセンブリ2を再び取り付け、LSCをリセットする。

【0030】図4Aと図4Bを参照すると、2種類の光ガイドの構成が示してある。これによって、光ガイド28はレーザダイオード発光器20と患者の皮膚S間の距離“r”を制御することができる。まず最初に、光ガイド28の平らな表面S'が患者の皮膚Sに押しつけられたとき、光ガイド28の平らな表面S'が患者の皮膚Sの接触領域を平らにするので、レーザダイオード発光器20と患者の皮膚S間の距離“r”は、光ガイド26により照射される皮膚領域全体にわたり一定である。図4Aに示す実施例では、レーザダイオード発光器20から出た光は直接光ガイド28の中を通過するので、距離“r”は単純にレーザダイオード発光器20から光ガイド28の表面S'に至る直線距離である。図4Bに示す実施例では、レーザダイオード14はその光を光偏向プリズムの表面30に投影し、プリズムの表面30は光を光ガイド28を通して患者の皮膚Sに至るように向ける。プリズム30を含むため、“r”の実効長さは $r=r_1+r_2$ に増加する。このようにプリズム構成を使うと、患者の皮膚に供給されるレーザダイオード14の光の強さを減らすことができる。プリズム30を含む結果、光の経路が長くなり、患者の皮膚Sの供給されるビームの面積が広がる。従って、システムが光偏向プリズムを含むときには、もっとエネルギーの高いレーザダイオードを使うことが可能になるかもしれない。皮膚Sに注がれるレーザ光の強さを減衰させるために、図4Aと図4Bの両方に示すように光ガイド28は選択性のフィルタ29を含んでもよい。選択性のフィルタ29は光減衰用中性密度フィルタ素子、または乳白色の半透明プラスチック材料のような光拡散性素子で、または両方を組み合わせて作ることができる。

【0031】レーザダイオードは通常自動電力制御(APC)フィードバック制御のために小さな内部監視用フォトダイオード21を含む。通常、少量のレーザ光がレーザダイオードの内部で反射または直接伝達によりレーザダイオード発光器20から監視用フォトダイオード21に向けてられている。NIRSプローブ内でレーザダイオードを使う

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とき、レーザ光は皮膚の表面Sからレーザダイオードに向けて反射戻りすることもありうるので、このために出力電力が変わる。これは監視用フォトダイオードにより生じる電流が通常非常に小さいので、皮膚からの反射戻り光が加わると、フォトダイオード電流が実質的に増えることがあり得るからである。その結果、反射戻り光量が変動するためにレーザの出力電力が予想外に変動することがあり得る。堅い光ガイド28は選択性フィルタ29を使って、皮膚の表面Sから反射して戻る変動性のレーザ光を減衰させることによって、レーザ出力の安定性を保っている。また、光ガイド28の反射性は弱く、監視用フォトダイオード21に向けて前もって算定された光量が反射して加わる。このため、監視用フォトダイオード21をより高いレベル、すなわちより低くないレベルに上げるにより、変動性の反射戻り光から生じる電流の効果が更に下げられる。

【0032】図5と図6はフォトダイオード検出窓8の周辺のEMIをシールドする機構を示す。前もって定められた厚さ、すなわち少なくとも約1mm、を有し、EMIシールドされた光学的に透明な窓板32がフォトダイオード検出器10の感光面34の上に設けてある。フォトダイオード検出器10はセラミックのカップ11の中に配置されている感光素子9を含む。針金網36が窓板32を形成している2個の光学的に透明な部材31と33との間に埋め込まれている。網36はレーザダイオード14から発して反射した光のうち少なくとも約60%をフォトダイオード10に届けることができるであろう。導電性金属箔のような非孔質のEMIシールド37が、フォトダイオードのリード線23を含むハウジングの非感光部分を囲んでいる。シリコンペースト、接着剤、またはその他の類似の材料から成る導電性ガスケット40を用いて、EMIシールドされた窓板32の網36と非孔質のEMIシールド37間に電気的に結合している。このタイプのシールドは望ましくないEMIにより生じるノイズを軽減し、2種類の方法によりフォトダイオードの信号対ノイズ比を改善する。針金網36と非孔質の導電性材料37の組み合わせがフォトダイオード10の周囲にファラディケージを形成し、また、光がフォトダイオード10の感光面34に届くことを可能にしている。前もって定められた厚さを有する、すなわち約1mmより厚い、光学的に透明な窓板32を使うことによって、フォトダイオードと生物組織間の分離距離が増えるので、更にEMIを減衰させることができる。このことがフォトダイオードの感光面34と人間の皮膚のような生物組織間の電磁結合と発生ノイズ電流とを減らす。EMIシールドされた光学的センサーを構成するために、チョメリックス社（マサチューセッツ州、ウォーバーン）から入手可能なEMIシールドされた窓を使うことができる。チョメリックス社の“Emi Clare”TM GP70 EMIシールドされた窓は60~70%の光を伝達し、1.66、2.00、3.00mmという種々の厚さの窓板が入手可能である。透明な窓板32と網36と

は窓Sに近い大きさで作り、フォトダイオード10の感光面34をおおう必要がある。感光面34の大きさは4~100mm²の範囲にすることができる。

【0033】EMIシールドの別の実施例では、針金網36はフォトダイオードの感光面34の上に直接置いてもよく、そのときには、約1mmより厚く、ガラスのような材料からできている光学的に透明で電気的に絶縁性の窓板32を針金網36の上に置いてよい。

【0034】図7と図8を参照すると、トランスジューサ装置2と一緒に使うことができる使い捨ての付属品粘着装置を2種類示してある。図7はトランスジューサ装置2を収納するのに使うことができる封筒42を示す。封筒42は2個の透明なプラスチック窓44と46とを有し、これらの窓はそれぞれレーザダイオードアセンブリ14と安全LED16、およびフォトダイオード・アセンブリ10と合うように大きさと位置が決められている。トランスジューサ装置2は開口48から封筒42の中に入れる。封筒42はまたいくつかの留め金50を含み、留め金50は封筒の中でトランスジューサ装置2を適所に保持するのに使われる。封筒42の表面52は接着剤で作られているか、または接着剤が塗られている。封筒42はゴムまたは黒いプラスチックのような光を通さない材料でできている。こうすることにより、もし透明な封筒を使ったら起こるであろうレーザダイオードとフォトダイオード間の光の直接伝達を防ぐ（すなわち光学的分路をなくす）。

【0035】図8は使い捨ての粘着性パッド54を示す。これはトランスジューサ装置2と患者の皮膚にくっつけて剥がすことができる。パッド54はまたゴムまたは黒いプラスチックでできていて、60のような両面の接着面を含む。このことによりパッド54がトランスジューサ装置2と患者の皮膚Sとに付着することができる。パッド54は2個の透明なプラスチック窓56と58とを有し、これらの窓はそれぞれレーザダイオード・アセンブリ14と安全LED16、およびEMIシールドされたフォトダイオード・アセンブリ18と合うように大きさと位置が決められている。封筒42とパッド54とは共に使用に先立って殺菌され、患者から取り除かれた後捨てることができる。

【0036】図9は新生児と一緒に使うのに適した、本発明に従って作られた伝達性NIRSトランスジューサ装置の実施例を示す。この実施例において、EMIシールドされたフォトダイオード・アセンブリ18は一方のシールドされたさや13に、レーザダイオード・アセンブリ14とLED16は他方のさや15に収容されている。さや13と15はケーブル38により接続され、ケーブル22はさや15からコントローラまで伸びている。ケーブル39の長さは脳の血液中酸素の伝達性監視ができるように、さや13と15が新生児の頭の両側に貼り付けることができるのに十分な長さにしてある。

【0037】図10、図11Aと図11Bは、離れて設置した3個のレーザダイオードと光ファイバー39とを採用したNI

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RSトランスジューサ装置の他の実施例を示す。光ファイバー39は離れて設置したレーザダイオードから発する光をLED16に隣接配置したプリズム30に向ける。フォトダイオードの窓8は前述したようにシールドされている。更に他の実施例では、別の光ファイバーを使って、離れた安全LEDから発する光をプリズム30に向けてもよい。プリズム30は、光ファイバーから伝達される光ビームの反射戻りを最小限にする光拡散表面35を備えることが好ましい。

【0038】図12はNIRSトランスジューサ装置のコネクタハウジング62の要素を示す。コネクタハウジング62はレーザダイオードの電力出力の相互交換を可能にする。ハウジング62はケーブル22によりレーザダイオード14と接続されているレーザダイオード自動電力制御ドライバ64を含む。レーザダイオード・シーケンサコントロール66はNIRSシステムプロセッサ68の一部を構成し、レーザダイオード14の多重パルス発光を制御する。各レーザダイオードの電力出力はそれぞれの自動電力制御ドライバにより調整される。3種類のレーザダイオードのピン出力構成が利用可能であり、各々が異なるタイプの自動電力制御ドライバを必要とする。このようにして、コネクタハウジング62内に自動電力制御ドライバ64を組み入れることによって、レーザダイオード14の選択に柔軟性を持たせている。

【0039】図13に示したコネクタアセンブリの他の実施例では、自動電力制御ドライバ64は調整可能な要素80と調整不可能な要素82とに分離することができる。この実施例では調整可能な要素80はコネクタハウジング62の中に配置しており、調整不可能な要素82はNIRSシステムプロセッサ68内に組み込まれている。調整可能な要素80はレーザの出力電力を調整するのに使う可変のポテンシオメータを含む。調整不可能な要素82は固定された半導体とディスクリート電子部品から成り、典型的に抵抗器とキャパシタである。図13はまたフォトダイオード前置増幅器76の別の置き方を示しており、コネクタハウジング62とアセンブリハウジング2との間に置かれて、ケーブル38に接続されている。前置増幅電力ケーブル84が前置増幅器76に電力を供給する。

【0040】コネクタハウジング62はまた校正パラメータ符号化機構70を含み、これはNIRSシステムプロセッサにNIRSトランスジューサ装置の特性に関する必要な情報を提供する。校正パラメータは、レーザダイオードの波長と電力、レーザダイオードとフォトダイオード間の分離距離、および採用した個々のNIRSトランスジューサ装置の特性に関する必要なその他の情報を含む。校正パラメータは前もって定めた値を持つ抵抗器、プログラム可能なリードオンリーメモリ、バーコード、またはその他の適当な符号化手段を用いて符号化することができる。符号化された情報はシステムプロセッサ68内の複合器74に伝達される。

【0041】フォトダイオードの前置増幅器76はコネクタハウジング62内に設けて、EMIシールドされたレーザダイオード・アセンブリ14から出力された光信号を増幅して、増幅した信号をNIRSシステムプロセッサ68の信号処理とレーザ安全連動制御部78に伝達するようにしてもよい。

【0042】図14に示したコネクタハウジングの更に他の実施例では、光ファイバNIRSプローブ39が採用され、レーザダイオード14がコネクタハウジング62の中に配置されている。カブラ86がレーザダイオード14と光ファイバの光導管39とを相互接続している。図12と図13に示した実施例で前述したように、自動電力制御ドライバ64もまたコネクタハウジング62の中に配置されている。

【0043】本発明のNIRSトランスジューサ装置2は以下のように動作する。アセンブリ2は多重レーザダイオード発光システムを有し、一度に1個のレーザだけが「オン」になってパルス発光し（ひとつの波長で発光）、前もって定めた搬送周波数で変調される。レーザダイオード14用の自動電力制御(APC)ドライバ64もまた電力の許容量を厳しく維持しつつ、あらかじめ定めた変調率で動作するであろう。すべてのレーザダイオード14が「オフ」になるという暗期間があり、このときオフセット電圧をサンプリングして差し引くことが可能になる。暗期間の長さはレーザダイオードが「オン」になっている期間より通常はるかに長い。したがって、レーザダイオードの全体のデューティサイクルは小さい。NIRSプローブの中に設けられているフォトダイオードは生物組織を照射したレーザ光を検出する。伝達インピーダンス・フォトダイオード前置増幅器が検出した光を電圧に変換する。第1段階は、搬送周波数を中心にして前もって定めた帯域を持つ帯域フィルタが検出した信号からノイズを除くことであろう。検出した信号の復調により更にノイズを減らして搬送周波数を除く。検出した光のレベルを所望の範囲に持ち上げるのに、利得調整可能な増幅器が使われるであろう。アナログ・デジタル変換器が各波長を復元し、変換器はレーザダイオードのパルス発光と同期したタイミング回路により制御される。得られたデータは、多変数モデファイド・ピア・ランバートの法則のアルゴリズムを使って、コンピュータで処理され、関心のある生理的パラメータが計算される。決められた生理的パラメータ、 ΔHb 、 ΔHbO_2 、 $\Delta\text{Total Hb}$ がモニタに表示される。

【0044】本発明のアセンブリにより採用されているNIRSアルゴリズムは多変数形式のピア・ランバートの法則に基づいている。ここでは3個のレーザダイオードが使われているので、マトリックス形式で表される。 HbO_2 と Hb の濃度の相対的变化はモデファイド・ピア・ランバートの法則を使って、定量化することができる。この法則は生物組織のような散乱の大きい媒体における光の減衰を考慮に入れている。散乱損失に起因する光の減衰を

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決定することは難しいので、発色団濃度の絶対的な測定は非常に挑戦的である。しかしながら、初期の基線からの差として光の減衰を測定することによって、散乱による光の減衰が消去される。モデファイド・ピア・ランバートの法則の多変数形式を使うには、2個の未知の発色団 ΔHbO_2 と ΔHb を決めるために、光の減衰を少なくとも2種類の波長で測定する必要がある。もし使用する波長の数が関心のある発色団の数と等しければ、クレーマの法則により解くことができる。もし使用する波長数が関心のある発色団の数よりも多ければ、前述のNIRSシステムの場合のように、アルゴリズムに最小2乗多重線形回帰法を使って関心のある発色団を解く。理論的には、測定波長の数が多ければ、それだけ発色団濃度を決定する際の誤差が少なくなる。したがって、前述のように、2種類の発色団を測定するのに3個のレーザダイオードを使うことにより、より正確に2個の発色団を測定する結果となるであろう。上述のシステムはまたチトクロームのような生物組織の第3の発色団を測定するように修正可能であることが理解されよう。光ファイバ素子がアセンブリに含まれているとき、好ましいレーザダイオードは連続波の縦形空洞表面発光レーザ(VCSEL)であり、光ファイバ素子がアセンブリに含まれていないとき、連続波のエッジ発光半導体レーザを使うことができる。

【0045】本発明の概念から逸脱することなく開示した実施例に多くの変更を施すことができるので、本発明は開示した実施例に限定されず、請求の範囲の記載に従うものである。

【図面の簡単な説明】

【図1】本発明により作られた反射型NIRSトランスジューサ装置の一実施例の平面図。

【図2】図1のトランスジューサ装置の側断面図。

【図3】図2のトランスジューサ装置に含まれるLEDとレーザダイオードの部分の拡大断面図。

【図4】図4Aはトランスジューサ装置のレーザダイオードと光ガイドと患者の皮膚との関係を示す拡大断面図。図4Bは図4Aと類似した断面図であるが、レーザダイオードの部分が修正され、光偏向プリズムを含む例を示す。

【図5】図2のトランスジューサ装置に含まれるフォトダイオードの部分の拡大断面図であって、フォトダイオード用のEMIシールド機構の詳細を示す。

【図6】図2のトランスジューサ装置のうちEMIシールドされたフォトダイオードの部分の拡大断面図。

【図7】図1のトランスジューサ装置のハウジングを収容して使うように設計された使い捨ての自己粘着性封筒の平面図。

【図8】図1のトランスジューサ装置のハウジングと一緒に使うように設計された使い捨ての自己粘着性パッドの平面図。

【図9】本発明に従って作られた伝達性NIRSトランスジューサ装置の他の実施例の平面図。

【図10】図1に類似した平面図であるが、本発明によるNIRSアセンブリの他の実施例を示す。

【図11】図11Aは図2に類似した断面図であるが、図10の実施例を示す。図11Bは図11Aの実施例の光源部を示す。

【図12】本発明に従って作られたNIRSトランスジューサ装置の構成図で、コネクタハウジングとNIRSアセンブリプロセッサが付随している。

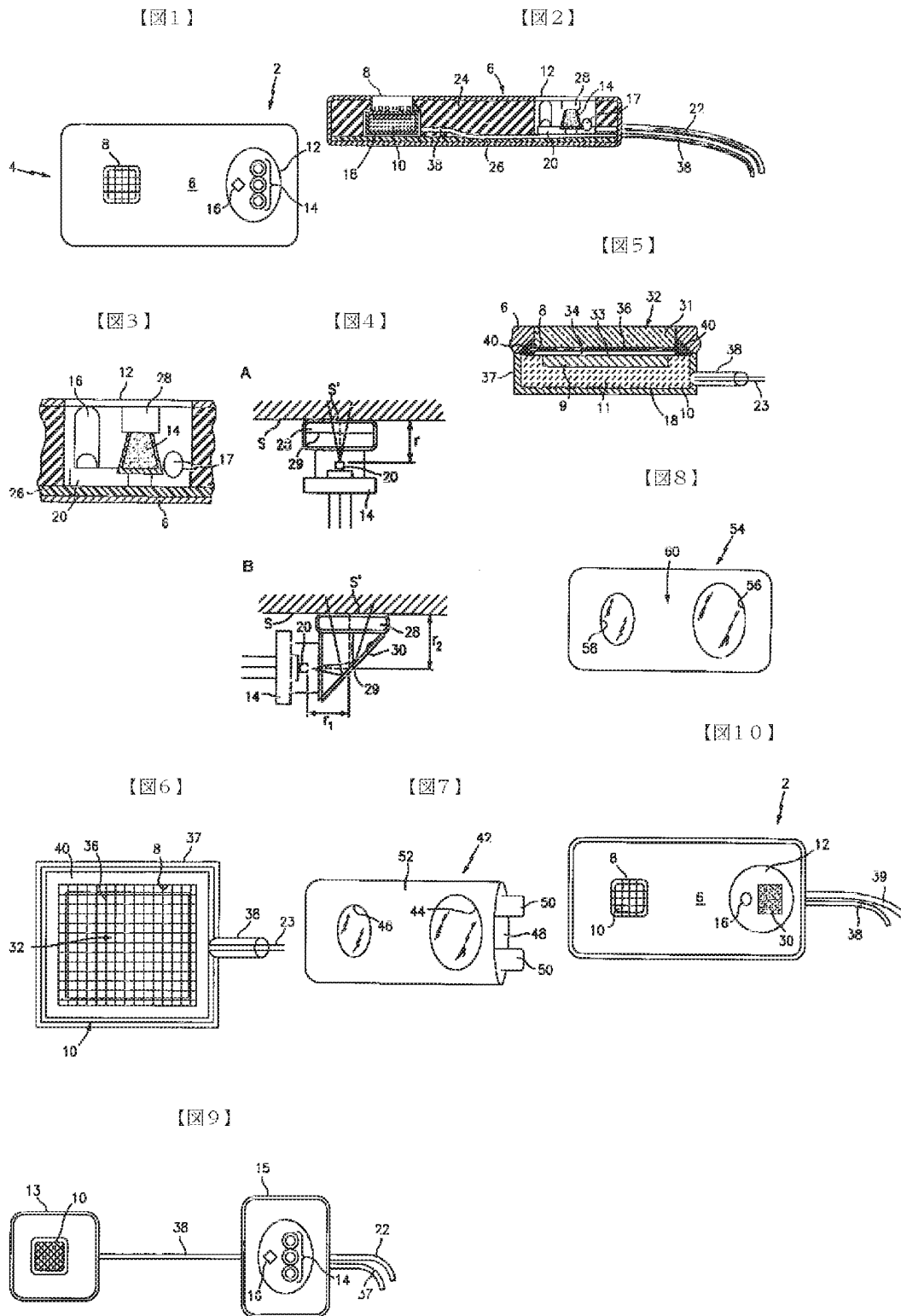
【図13】図12に類似したNIRSトランスジューサ装置の構成図であるが、レーザ電力制御ドライバとシステムの前置増幅部とが分離されて、システムの前置増幅部がコネクタハウジングとアセンブリハウジングとの間に設置されている。

【図14】図13に類似したNIRSトランスジューサ装置の構成図であるが、図10と図11Aの実施例の特徴を組み込んでいる。

【符号の説明】

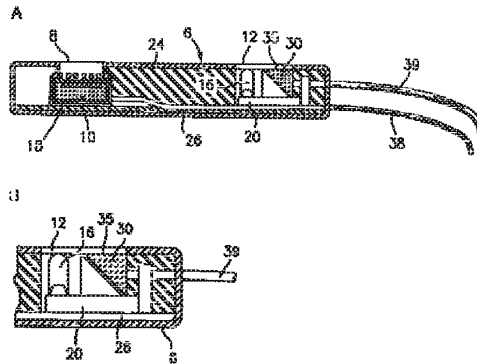
- 2 NIRS光トランスジューサ装置
- 4 ハウジング
- 8 窓
- 10 フォトダイオード検出器
- 14 レーザダイオード・クラスタ
- 16 安全LED
- 17 サーミスタ
- 20 発光器
- 28 光ガイド
- 30 プリズム
- 37 EMIシールド
- 42 使い捨ての粘着性封筒
- 54 使い捨ての粘着性パッド
- 62 コネクタハウジング
- 64 自動電力制御ドライバ
- 68 NIRSシステムプロセッサ

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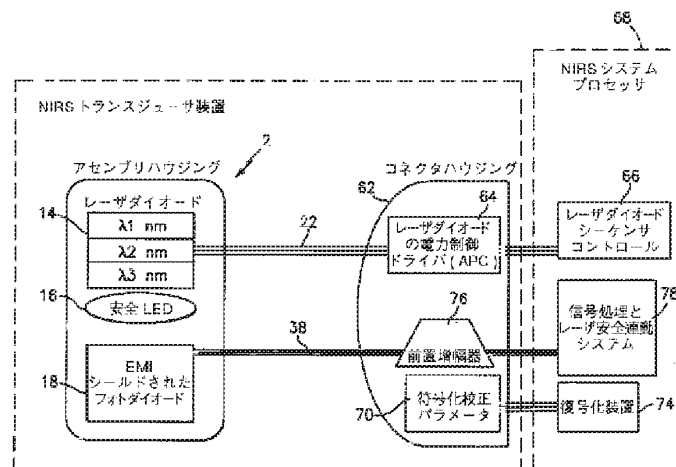


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【図11】

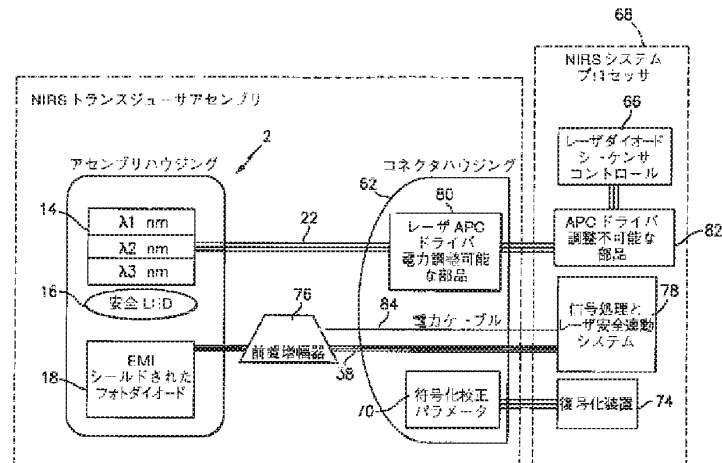


【図12】

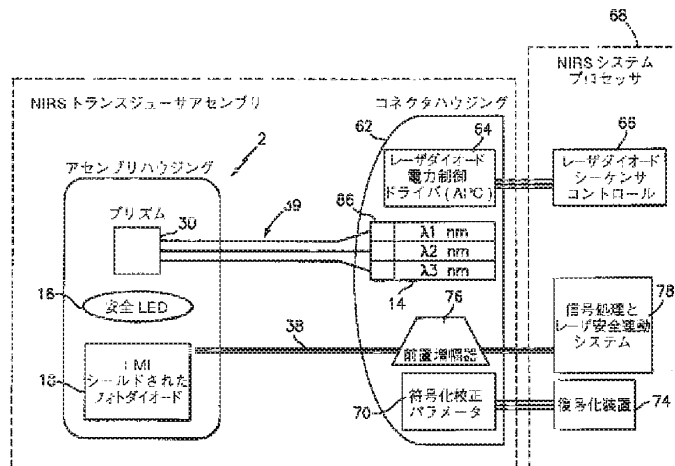


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【図13】



【図14】



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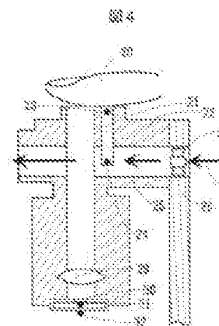
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(54)BLOOD SUGAR LEVEL MEASURING APPARATUS

(57)Abstract

PROBLEM TO BE SOLVED: To measure a blood sugar level with high accuracy and high reproducibility in a short time in a non-invasive blood sugar level measuring apparatus.
SOLUTION: A bar-like member 21 is disposed at a part with which the bulb 20 of a finger which is a detected part, comes in contact, and the periphery of the bar-like member 21 is covered with a heat insulating material 22 lower in heat conductivity than the bar-like member 21. A part of the bar-like member 21 including a thermistor 24 is installed within a duct 25 provided in a measuring section. Room temperature air 27 is led inside from the outside of a casing 26 by a fan 28 provided in the duct, and the room temperature air 27 is applied to a part of the bar-like member 21 including the thermistor 24 to cool it.

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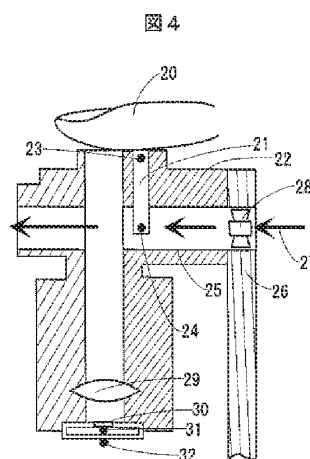
(54) 【発明の名称】 血糖値測定装置

(57) 【要約】

【課題】無侵襲による血糖値測定装置において、血糖値を短時間で高精度かつ再現性良く測ること。

【解決手段】被検部である指の腹20が接触する部分には棒状部材21を配置し、棒状部材21の周囲を棒状部材21の熱伝導率より低い断熱材22で覆い囲む。サーミスタ24を含む棒状部材21の一部分を、測定部内に設けたダクト25内に設置し、筐体26の外から室温の空気27をダクト内に設けたファン28で内部へ導入し、サーミスタ24を含む棒状部材21の一部分に室温空気27を当てて、冷却する。

【選択図】 図4



(2)

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【特許請求の範囲】

【請求項1】

環境温度を測定する環境温度検出器と、
一端に体表面接触部を有する熱伝導部材と、
前記体表面からの輻射熱を測定する輻射熱検出器と、
前記熱伝導部材の前記体表面接触部に隣接して設けられた第1の温度検出器と、
前記熱伝導部材の他端に隣接して設けられた第2の温度検出器と、
前記熱伝導部材の他端側を冷却する冷却手段と、
前記体表面接触部に向けて少なくとも2つの異なる波長の光を照射する光源と、
前記光が前記体表面で反射されて生じる反射光を検出する光検出器と、
前記第1の温度検出器、前記第2の温度検出器、前記環境温度検出器、前記輻射熱検出器及び前記光検出器各々の出力を各々パラメータに変換する変換部と、前記パラメータと血糖値との関係を予め記憶し、前記パラメータを前記関係に適用して血糖値を算出する処理部とを有する演算部と、

前記演算部から出力される結果を表示する表示部とを備えることを特徴とする血糖値測定装置。

【請求項2】

前記熱伝導部材の熱伝導率は、当該熱伝導部材を囲む部材の熱伝導率より大きいことを特徴とする請求項1記載の血糖値測定装置。

【請求項3】

前記冷却手段は、前記熱伝導部材の他端側に向けて外気を導入するダクトとファンとを有することを特徴とする請求項1記載の血糖値測定装置。

【請求項4】

前記冷却手段は、ペルチェ素子、前記ペルチェ素子を挟んで設けられた冷却側ヒートシンク及び放熱側ヒートシンクを有することを特徴とする請求項1記載の血糖値測定装置。

【請求項5】

前記放熱側ヒートシンクにフィンを備えるヒートパイプが接続され、前記フィンを空冷するファンを有することを特徴とする請求項4記載の血糖値測定装置。

【請求項6】

前記放熱側ヒートシンクは液冷ジャケットであり、前記液冷ジャケットに直列に接続されるポンプ及びラジエータを有することを特徴とする請求項4記載の血糖値測定装置。

【請求項7】

前記体表面接触部の飽和温度を、前記第1の温度検出器によって測定された前記体表面接触部の温度上昇曲線を用いて演算する手段を有することを特徴とする請求項1～6のいずれか1項記載の血糖値測定装置。

【請求項8】

前記光は、血中ヘモグロビン濃度及びヘモグロビン酸素飽和度の測定に用いることを特徴とする請求項1記載の血糖値測定装置。

【発明の詳細な説明】

【技術分野】

【0001】

本発明は、無侵襲で血液中の血糖値を測定する血糖値測定装置に関する。

【背景技術】

【0002】

Hilsonらは、糖尿病患者にグルコースを静脈注射すると、その後に顔面及び舌下温度が変化することを報告している（非特許文献1）。Scottらは、糖尿病患者と体温調節の問題を論じている（非特許文献2）。これらの研究知見に基づき、Choらは、採血を伴わずに、温度測定によって血中グルコース濃度を求める方法及び装置を提案している（特許文献1、2）。

【0003】

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また、採血を伴わないグルコース濃度の算出に関してはさらに様々な試みがなされている。例えば、測定部位へ3つの波長の近赤外光を照射して透過光強度を検出するとともに生体温度を検出し、吸光度の2次微分値の代表値を求め、予め定めた基準温度からの生体温度のずれに対応して上記代表値を補正し、補正された代表値に相当する血糖濃度を求める方法が提案されている（特許文献3）。また、測定部位において生体温度をモニタしながら加熱もしくは冷却を行い、温度が変化する瞬間に光照射に基づく減光度を測定して、減光度の温度依存性の原因となっているグルコース濃度を測定する装置が提供されている（特許文献4）。また、参照光と試料に照射した後の透過光との出力比を取り、出力比の対数と生体の温度との1次式からグルコース濃度を算出する装置が報告されている（特許文献5）。

【非特許文献1】Diabete & Metabolisme, "Facial and sublingual temperature changes following intravenous glucose injection in diabetics" by R.M. Hilson and T.D. R. Hockaday, 1982, 8, 15-19

【非特許文献2】Can. J. Physiol. Pharmacol., "Diabetes mellitus and thermoregulation", by A.R. Scott, T. Bennett, I.A. MacDonald, 1987, 65, 1365-1376

【特許文献1】米国特許第5, 924, 996号公報

【特許文献2】米国特許第5, 795, 305号公報

【特許文献3】特開2000-258343号公報

【特許文献4】特開平10-33512号公報

【特許文献5】特開平10-108857号公報

【発明の開示】

【発明が解決しようとする課題】

【0004】

血液中のグルコース（血糖）は細胞内でグルコース酸化反応に使われ、生体の維持に必要なエネルギーを産生する。特に基礎代謝の状態においては、産生されたエネルギーの大部分は体温を維持するための熱エネルギーとなるのであるから、血中グルコース濃度と体温との間には何らかの関係があることは予想されるところではある。しかし、病気による発熱を考えれば明かなように、体温は血中グルコース濃度以外の要因によっても変動する。従来、採血を伴わずに温度測定によって血中グルコース濃度を求める方法が提案されてはいたが、十分な精度を有するものとは言い難かった。

【0005】

本発明は、被験者の温度データをもとに採血を伴わずに高精度で血中グルコース濃度を求める方法及び装置を提供することを目的とする。

【課題を解決するための手段】

【0006】

血糖は、血管系、特に毛細血管によって全身の細胞に供給されている。ヒトの体内には複雑な代謝経路が存在するが、グルコース酸化は、根源的には血糖と酸素が反応し、水と二酸化炭素とエネルギーを産生する反応である。ここでいう酸素とは血液から細胞へ供給される酸素であり、酸素供給量は血液中のヘモグロビン濃度と、ヘモグロビン酸素飽和度と、血流量によって決まる。一方、グルコース酸化によって体内で産生した熱は、対流、熱輻射、伝導等の形で体から奪われる。我々は、体温は体内でのグルコース燃焼によるエネルギー産生量、すなわち熱産生とこれら熱放散のバランスによって決まると考え、次のようなモデルを考えた。

(1) 熱産生量と熱放散量とは同等視される。

(2) 熱産生量は、血中グルコース濃度と酸素供給量の関数である。

(3) 酸素供給量は、血中ヘモグロビン濃度と、血中ヘモグロビン酸素飽和度と、毛細血管内の血流量によって決まる。

(4) 熱放散量は、主に熱対流と熱輻射によって決まる。

【0007】

このモデルに従い、体表を熱測定し、同時に血液中の酸素濃度に関するパラメータ及び

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血流量に関するパラメータを測定し、これらの測定結果を用いて血糖値を高精度に求められることを見出した。一例として、上記パラメータを求めるための測定は、ヒトの体の一部、例えば指先を測定対象とし、対流と輻射に関するパラメータは指先を熱測定することにより求めることができる。また血中ヘモグロビン濃度および血中ヘモグロビン酸素飽和度に関するパラメータは、血液中のヘモグロビンを分光学的に測定し、酸素と結合しているヘモグロビンと結合していないヘモグロビンの比率により求めることができる。さらに血流量に関するパラメータは、皮膚からの熱流量を測定することにより求めることができる。

【0008】

上記目的は、環境温度を測定する環境温度検出器と、一端に体表面接触部を有する熱伝導部材と、体表面からの輻射熱を測定する輻射熱検出器と、熱伝導部材の体表面接触部に隣接して設けられた第1の温度検出器と、熱伝導部材の他端に隣接して設けられた第2の温度検出器と、熱伝導部材の他端側を冷却する冷却手段と、体表面接触部に向けて少なくとも2つの異なる波長の光を照射する光源と、光が体表面で反射されて生じる反射光を検出する光検出器と、第1の温度検出器、第2の温度検出器、環境温度検出器、輻射熱検出器及び光検出器各々の出力を各々パラメータに変換する変換部と、パラメータと血糖値との関係を予め記憶し、前記パラメータを前記関係に適用して血糖値を算出する処理部とを有する演算部と、演算部から出力される結果を表示する表示部とを備える血糖値測定装置によって達成される。

【0009】

ここで、熱伝導部材の熱伝導率は、当該熱伝導部材を囲む部材の熱伝導率より大きい。冷却手段は、熱伝導部材の他端側に向けて外気を導入するダクトとファンとを有してもよい。また、冷却手段は、ペルチェ素子、ペルチェ素子を挟んで設けられた冷却側ヒートシンク及び放熱側ヒートシンクを有してもよい。さらに、体表面接触部の飽和温度を、第1の温度検出器によって測定された体表面接触部の温度上昇曲線を用いて演算する手段を有してもよい。

【発明の効果】

【0010】

本発明によると、無侵襲による血糖値測定装置において、血糖値を短時間で高精度かつ再現性良く測定することが可能となる。

【発明を実施するための最良の形態】

【0011】

最初に、前記モデルの具体化について説明する。熱放散量について考えると、その主因である対流熱伝達は、環境温度（室温）と体表温の間の温度差が関係し、他の要因である輻射による熱放散量は、ステファン・ボルツマンの法則により体表面の絶対温度の4乗に比例する。従って、人体からの熱放散量には、室温と体表温が関係していることが分かる。一方、熱生産量に関係するもう一つの要因である酸素供給量は、ヘモグロビン濃度と、ヘモグロビン酸素飽和度と、血流量の積として表される。

【0012】

ここでヘモグロビン濃度は、酸素結合型ヘモグロビンと還元（脱酸素）型ヘモグロビンのモル吸光係数が等しくなる波長（等吸光波長）の吸光度より測定できる。ヘモグロビン酸素飽和度は、上記の等吸光波長の吸光度と、酸素結合型ヘモグロビンと還元（脱酸素）型ヘモグロビンのモル吸光係数の比が既知の最低限他の1波長の吸光度を測定し、連立方程式を解くことにより測定できる。すなわち、ヘモグロビン濃度と、ヘモグロビン酸素飽和度は、最低2波長の吸光度測定によって得ることができる。

【0013】

残るのは血液の流量である。血流量は種々の方法で測定することが可能であるが、その測定方法の一例について以下説明する。

【0014】

図1は、本装置における血流量の測定原理を示す熱回路網の概念図である。人体は、そ

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の深部温度を37℃一定に保つよう、人体外界と熱交換している。そこで、人体の深部温度 T_c と、体表面温度 T_1 間に流れる熱流量 Q を測定すれば、 T_c と T_1 間の熱抵抗 R_1 が求まる。この熱抵抗、すなわち人体組織の熱伝導率は、血流量と相関があるため、血流量が推定できる。この熱流量 Q を測定するためには、ある一定の熱抵抗 R_2 を有するブロックを用意し、体表面と、体表面に接触したブロックの両端の温度(T_1 及び T_2)を測定すれば良い。ブロックを通過する熱は、 T_2 から熱抵抗 R_3 を経由して、室温 T_4 へ放熱される。

熱抵抗 R_1 は次式(1)で求められる。

【0015】

【数1】

$$R_1 = (T_c - T_1)R_2 / (T_1 - T_2) \quad \dots\dots(1)$$

【0016】

ここで温度 T_c は上述した通り、37℃一定であり、熱抵抗 R_2 を固定し、温度 T_1 と T_2 を測定すれば、熱抵抗 R_1 が求まり、熱抵抗 R_1 と相関がある血流量が推定できる。

【0017】

また、輻射温度計により体表面温度 T_3 を測定することで、体表面からの輻射伝熱量も推定できる。熱抵抗 R_1 から、血流量を示唆するパラメータ X_5 を求める。

【0018】

以上の説明から、前記モデルによって血中グルコース濃度を求めるために必要な測定量は、室温(環境温度)、体表面に接触されるブロック内の飽和温度勾配、体表面からの輻射による温度及び最低限2波長の吸光度であることが分かる。

【0019】

図2は、本装置における各種センサによる測定値と、それから導出されるパラメータとの関係を図示した説明図である。図1で述べた通り、体表面と接触するブロックを用意し、その2箇所に設置した2個の温度センサによって2種類の温度 T_1 と T_2 を測定する。別途、体表面の輻射温度 T_3 と室温 T_4 を測定する。また、ヘモグロビンの吸収に関係する少なくとも2種類の波長で吸光度 A_1 、 A_2 を測定する。温度 $T_1 \sim T_4$ から血流量に関するパラメータが得られ、温度 T_3 から輻射伝熱量に関するパラメータが得られ、温度 T_3 と温度 T_4 から対流伝熱量に関するパラメータが各々得られる。また吸光度 A_1 からヘモグロビン濃度に関するパラメータが得られ、吸光度 A_1 と A_2 からヘモグロビン酸素飽和度に関するパラメータが得られる。

【0020】

図3は、本発明による無侵襲血糖値測定装置の上面図である。この無侵襲血糖値測定装置100では、体表面として指先の腹の皮膚を使うが、他の体表面を使うことも可能である。無侵襲血糖値測定装置100上面には操作部11、測定対象となる指が置かれる測定部12、測定結果の表示、装置の状態や測定値等を表示する表示部13が設けられている。操作部11には、装置の操作を行うための4個の押しボタン11a～11dが配置されている。測定部12にはカバー14が設けられ、カバー14を開けると(図はカバーを開けた状態を示す)、楕円型の周縁を持つ指置き部15がある。指置き部15の中には、輻射温度センサ部の開口端16と接触温度センサ部17と光学センサ部18がある。

【0021】

前述した熱抵抗 R_1 を求めるためには、定常状態での温度 T_1 、 T_2 が必要であるが、実際の測定では下記の点を考慮する必要がある。

- (1) 指からブロック以外へ流れる漏れ熱流量が大きいと、測定誤差が大きくなる。
- (2) 定常状態となるまで、長時間測定する必要がある。

【0022】

そこで、上記点を解決する本発明の装置の測定部断面図を図4に示す(光学センサ部は省略)。被検部である指の腹20が接触する部分には棒状部材(ブロック)21を配置し、棒状部材21の周囲は、熱伝導率が棒状部材21の熱伝導率より低い断熱材22で覆い

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囲む。こうすることで、棒状部材21以外へ流れる漏れ熱流量を低減できる。さらに、棒状部材21の指の腹20が接触する部分にサーミスタ23（温度T1）を、そして棒状部材21のもう一端にサーミスタ24（温度T2）を設置し、サーミスタ24を含む棒状部材21の一部分を、測定部に設けたダクト25内に設置し、筐体26の外から室温の空気27をダクト内に設けたファン28で筐体26の内部へ導入し、サーミスタ24を含む棒状部材21の一部分に室温空気27を当てる構造とする。

【0023】

これは、図1に示す、温度T2と室温T4との間の熱抵抗R3を低減することを意味し、温度が定常になるまでの時間を短縮する効果がある。また、無侵襲血糖値測定装置100内に測定部以外の実装部品（半導体チップや表示部）から発生する熱が、測定部のサーミスタ23、24へあふられ、測定値に悪影響を生じることも防止できる。なお図4では、室温空気27をファン28でダクト25に押し込み、筐体26の外へ排出する構造にしたが、それに限ったものではなく、室温空気27をファン28でダクト25を通じて、筐体26の外から吸込む構造もある。

【0024】

指の腹20を見通せる装置内部の位置に赤外線レンズ29が置かれ、赤外線レンズ29の下方に赤外線透過窓30を介して焦電検出器31が配置されている。また、焦電検出器31に近接して別のサーミスタ32が設置されている。これらにより、輻射温度T3及び室温T4を測定する。

【0025】

図5に、温度T1とT2の温度上昇曲線の一例を示す（室温T4=20℃）。横軸が時間で、縦軸が温度である。図中、実線が温度T1、破線が温度T2で、●が室温下での自然冷却、○が図4で述べた、ファンによる強制冷却の場合を示す。

【0026】

温度T1、T2は時間の経過と共に上昇し、ある一定値に飽和する。飽和した温度T1とT2を測定することで、上式(1)から熱抵抗R1を算出するが、自然冷却の場合、飽和するまでの時間は120秒程度を要するのに対し、強制冷却の場合では約60秒と自然冷却の場合と比して半分となり、測定時間を大幅に短縮できることが分る。

【0027】

図6に、本発明の第二実施例を示す。この構成は、測定環境が空調風等により不安定な場合や、更なる高精度、また更に短時間で測定する必要がある場合に有効である。すなわち、サーミスタ24側の棒状部材21の一部分を、熱伝導率の非常に高い材料、例えば銅やアルミでできた冷却側ヒートシンク40に接続させる。そしてヒートシンクを一定温度に冷却するためのペルチェ素子41を冷却側ヒートシンク40と接続させる。さらにペルチェ素子41のもう一方側には放熱側ヒートシンク42を接続させ、放熱側ヒートシンク42にヒートパイプ43を接続する。ヒートパイプ43にフィン44を設け、そのフィン44を無侵襲血糖値測定装置100内に設けたダクト45内に配置する。そしてファン46を用いて、外気をダクト45に導入し、フィン44を冷却する。一方、ペルチェ素子41は、他から影響を受けずに室温を検知する温度計（図示せず）からの信号で、その室温と同じかつ一定になるよう制御され、温度T2を安定させる。こうすることで、外部環境が変動する場所でも、温度T1、T2を短時間で高精度に測れる利点を有する。

【0028】

上記説明は、熱抵抗R3を、図4の実施例より、さらに低減する内容であるが、この実施例の別の効果として、図7に示す温度T1の温度上昇曲線において（横軸は時間、縦軸は初期状態からの温度差で、実線が熱抵抗R3の大きい場合、また破線が熱抵抗R3の小さい場合、そして、○が各々の温度上昇曲線を指数関数で近似した場合を示す）、熱抵抗R3を低減することで、指の腹20を棒状部材21に置いてからの温度上昇曲線が指数関数近似に近づくことが分る。従って、指の腹20を温度T1が飽和するまで棒状部材21に置かなくても、ある程度の時間を経た温度上昇曲線を用いて温度T1の飽和値を指数関数で精度良く推算することが可能となる。

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【0029】

また、ヒートパイプ43の形状を任意に変えることで、ファン46の設置場所を任意に変えることができ、測定部のレイアウトの自由度も増やすことができる。

【0030】

図8に本発明の第三実施例を示す。これは、ペルチェ素子41の放熱に液冷構造を用いたものである。即ち、ペルチェ素子41の放熱側に液冷ジャケット50を接続させ、ポンプ51、ラジエータ52をチューブ53で各々直列に接続して液冷循環とする。こうすることで、ポンプ51やラジエータ52の配置の自由度を増すことができる。

【0031】

次に光学測定について述べる。図3に示す光学センサ部18は、酸素供給量を求めるために必要なヘモグロビン濃度とヘモグロビン酸素飽和度を測定するためのものである。ヘモグロビン濃度とヘモグロビン酸素飽和度を測定するには最低2波長での吸光度測定が必要であり、図9は2個の光源62、63と1個の検出器64によって2波長測定を行うための構成例を示している。

【0032】

光学センサ部18には、2個の光ファイバー60、61の端部が位置する。光ファイバー60は光照射用の光ファイバーであり、光ファイバー61は受光用の光ファイバーである。光ファイバー60は支線となるファイバー60a、60bにつながり、それらの末端には2つの波長の発光ダイオード62、63が配されている。受光用光ファイバー61の末端には、フォトダイオード64が配されている。発光ダイオード62は波長810nmの光を出し、発光ダイオード63は波長950nmの光を出す。波長810nmは、酸素結合型ヘモグロビンと還元型(脱酸素)型ヘモグロビンのモル吸光係数が等しくなる等吸光波長であり、波長950nmは酸素結合型ヘモグロビンと還元型ヘモグロビンのモル吸光係数の差が大きい波長である。

【0033】

2個の発光ダイオード62、63は時分割的に発光し、発光ダイオード62、63から発生された光は光照射用光ファイバー60から被検者の指の腹20に照射される。指に照射された光は指の腹20の皮膚で反射し、受光用光ファイバー61に入射してフォトダイオード64によって検出される。指に照射された光が指の皮膚で反射されるとき、一部の光は皮膚を通して組織内部に侵入し、毛細血管を流れる血液中のヘモグロビンによる吸収を受ける。フォトダイオード64による測定データは反射率Rであり、吸光度は近似的に $\log(1/R)$ で計算される。波長810nmと波長950nmの光について各々照射を行い、各々についてRを測定し、 $\log(1/R)$ を求めることにより、波長810nmの吸光度A1と波長950nmの吸光度A2が測定される。

【0034】

還元型ヘモグロビン濃度を[Hb]、酸素結合型ヘモグロビン濃度を[HbO2]とすると、吸光度A1および吸光度A2は次式(2)で表される。

【0035】

【数2】

$$\begin{aligned}
 A_1 &= a \times ([Hb] \times A_{Hb}(810nm) + [HbO_2] \times A_{HbO_2}(810nm)) \\
 &= a \times ([Hb] + [HbO_2]) \times A_{HbO_2}(810nm) \\
 A_2 &= a \times ([Hb] \times A_{Hb}(950nm) + [HbO_2] \times A_{HbO_2}(950nm)) \\
 &= a \times ([Hb] + [HbO_2]) \times \left(1 - \frac{[HbO_2]}{[Hb] + [HbO_2]}\right) \times A_{Hb}(950nm) + \frac{[HbO_2]}{[Hb] + [HbO_2]} \times A_{HbO_2}(950nm) \\
 &\dots\dots(2)
 \end{aligned}$$

【0036】

AHb(810nm)とAHb(950nm)、AHbO2(810nm)とAHbO2(950nm)はそれぞれ還元型ヘモグロビン、酸素結合型ヘモグロビンのモル吸光係数であり各波長で既知である。aは比例係数であ

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る。ヘモグロビン濃度 $[Hb] + [HbO_2]$ 、ヘモグロビン酸素飽和度 $[HbO_2] / ([Hb] + [HbO_2])$ は上式から次のように求められる。

【0037】

【数3】

$$\begin{aligned} [Hb] + [HbO_2] &= \frac{A_1}{a \times A_{HbO_2}(810nm)} \\ \frac{[HbO_2]}{[Hb] + [HbO_2]} &= \frac{A_2 \times A_{HbO_2}(810nm) - A_1 \times A_{Hb}(950nm)}{A_1 \times (A_{HbO_2}(950nm) - A_{Hb}(950nm))} \end{aligned} \quad \text{.....(3)}$$

【0038】

なお、ここでは2波長による吸光度測定によってヘモグロビン濃度とヘモグロビン酸素飽和度を測定する例について説明したが、3波長以上で吸光度を測定することによって、妨害成分の影響を低減し測定精度を高めることも可能である。

【0039】

図10は、装置内におけるデータ処理の流れを示す概念図である。本例の装置には、サーミスタ23、サーミスタ24、焦電検出器31、サーミスタ32、フォトダイオード64からなる5個のセンサがある。フォトダイオード64では波長810nmの吸光度と波長950nmの吸光度を測定するため、装置には6種類の測定値が入力されることになる。

【0040】

5種類のアナログ信号は、それぞれA1～A5の増幅器を経由して、AD1～AD5のアナログ・デジタル変換器によってデジタル変換される。デジタル変換された値からパラメータ x_i ($i=1, 2, 3, 4, 5$) が計算される。 x_i を具体的に表記すると以下のとおりとなる ($a_1 \sim a_5$ は比例係数)。

【0041】

【数4】

熱輻射に比例したパラメータ

$$x_1 = a_1 \times (T_1)^4$$

熱対流に比例したパラメータ

$$x_2 = a_2 \times (T_4 - T_3)$$

ヘモグロビン濃度に比例したパラメータ

$$x_3 = a_3 \times \left(\frac{A_1}{a \times A_{HbO_2}(810nm)} \right)$$

ヘモグロビン飽和度に比例したパラメータ

$$x_4 = a_4 \times \left(\frac{A_2 \times A_{HbO_2}(810nm) - A_1 \times A_{Hb}(950nm)}{A_1 \times (A_{HbO_2}(950nm) - A_{Hb}(950nm))} \right)$$

血流量に比例したパラメータ

$$x_5 = a_5 / R_1 \quad \text{.....(4)}$$

【0042】

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つづいて、実際の多数の健常者および糖尿病患者のデータから得られたパラメータ x_i の平均値と標準偏差から正規化パラメータを算出する。各パラメータ x_i から正規化パラメータ X_i ($i=1, 2, 3, 4, 5$) を次の式で計算する。

【0043】

【数5】

$$X_i = \frac{x_i - \bar{x}_i}{SD(x_i)} \quad \dots\dots(5)$$

x_i : パラメータ

\bar{x}_i : パラメータの平均値

$SD(x_i)$: パラメータの標準偏差

【0044】

前述の5つの正規化パラメータをもって、最終的な表示を行うためのグルコース濃度への変換計算が行われる。処理計算に必要なプログラムは、装置に組み込まれたマイクロプロセッサに内蔵されたROMに記憶されている。また、処理計算に必要なメモリー領域は、同様に装置に組み込まれているRAMに確保される。計算処理された結果は、液晶表示部に表示される。

【0045】

ROMには処理計算に必要なプログラム構成要素として、特にグルコース濃度Cを求めるための関数が入っている。この関数は以下のように定められたものである。まず、Cは以下の式(6)で表現される。 a_i ($i=0, 1, 2, 3, 4, 5$) は、複数の測定データから前もって決定されている。 a_i を求める手順は以下の通りである。

- (1) 正規化パラメータとグルコース濃度Cの関係を示す重回帰式を作成する。
 - (2) 最小二乗法によって得られた式から正規化パラメータに関する正規方程式（連立方程式）を求める。
 - (3) 正規方程式から係数 a_i ($i=0, 1, 2, 3, 4, 5$) の値を求め、重回帰式に代入する。
- 初めに、グルコース濃度Cと正規化パラメータ X_1, X_2, X_3, X_4, X_5 の関係を示す次の回帰式(6)を作る。

【0046】

【数6】

$$\begin{aligned} C &= f(X_1, X_2, X_3, X_4, X_5) \\ &= a_0 + a_1 X_1 + a_2 X_2 + a_3 X_3 + a_4 X_4 + a_5 X_5 \quad \dots\dots(6) \end{aligned}$$

【0047】

つづいて、酵素電極法によるグルコース濃度測定値 C_i との誤差が最小になるような重回帰式を求めるため、最小二乗法を用いる。残差の二乗和をDとすると、Dは次式で表される。

【0048】

【数7】

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$$\begin{aligned}
 D &= \sum_{i=1}^n d_i^2 \\
 &= \sum_{i=1}^n (C_i - f(X_{i1}, X_{i2}, X_{i3}, X_{i4}, X_{i5}))^2 \\
 &= \sum_{i=1}^n \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\}^2 \quad \dots\dots(7)
 \end{aligned}$$

【0049】

残差の二乗和Dが最小になるのは、式(7)を a_0, a_2, \dots, a_5 で偏微分してゼロとなるときなので、次式(8)が得られる。

【0050】

【数8】

$$\begin{aligned}
 \frac{\partial D}{\partial a_0} &= -2 \sum_{i=1}^n \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\} = 0 \\
 \frac{\partial D}{\partial a_1} &= -2 \sum_{i=1}^n X_{i1} \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\} = 0 \\
 \frac{\partial D}{\partial a_2} &= -2 \sum_{i=1}^n X_{i2} \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\} = 0 \\
 \frac{\partial D}{\partial a_3} &= -2 \sum_{i=1}^n X_{i3} \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\} = 0 \\
 \frac{\partial D}{\partial a_4} &= -2 \sum_{i=1}^n X_{i4} \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\} = 0 \\
 \frac{\partial D}{\partial a_5} &= -2 \sum_{i=1}^n X_{i5} \{C_i - (a_0 + a_1 X_{i1} + a_2 X_{i2} + a_3 X_{i3} + a_4 X_{i4} + a_5 X_{i5})\} = 0 \quad \dots\dots(8)
 \end{aligned}$$

【0051】

$C, X_1 \sim X_5$ の平均値を $C_{mean}, X_{1mean} \sim X_{5mean}$ とすると $X_{imean} = 0$ ($i=1 \sim 5$) であるので、式(6)から式(9)が得られる。

【0052】

【数9】

$$\begin{aligned}
 a_0 &= C_{mean} - a_1 X_{1mean} - a_2 X_{2mean} - a_3 X_{3mean} - a_4 X_{4mean} - a_5 X_{5mean} \\
 &= C_{mean} \quad \dots\dots(9)
 \end{aligned}$$

【0053】

また、正規化パラメータ間の変動・共変動は、式(10)で表され、正規化パラメータ X_i ($i=1 \sim 5$) と C との共変動は式(11)で表される。

【0054】

【数10】

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$$S_{ij} = \sum_{k=1}^n (X_{ki} - X_{i\text{mean}})(X_{kj} - X_{j\text{mean}}) = \sum_{k=1}^n X_{ki} X_{kj} \quad (i, j = 1, 2, \dots, 5) \quad \dots\dots(10)$$

$$S_{iC} = \sum_{k=1}^n (X_{ki} - X_{i\text{mean}})(C_k - C_{\text{mean}}) = \sum_{k=1}^n X_{ki} (C_k - C_{\text{mean}}) \quad (i = 1, 2, \dots, 5) \quad \dots\dots(11)$$

【0055】

式(9)、式(10)、式(11)を式(8)に代入して整理すると、連立方程式（正規方程式）(12)が得られ、これを解くことでa1～a5が求まる。

【0056】

【数11】

$$\begin{aligned} a_1 S_{11} + a_2 S_{12} + a_3 S_{13} + a_4 S_{14} + a_5 S_{15} &= S_{1C} \\ a_1 S_{21} + a_2 S_{22} + a_3 S_{23} + a_4 S_{24} + a_5 S_{25} &= S_{2C} \\ a_1 S_{31} + a_2 S_{32} + a_3 S_{33} + a_4 S_{34} + a_5 S_{35} &= S_{3C} \\ a_1 S_{41} + a_2 S_{42} + a_3 S_{43} + a_4 S_{44} + a_5 S_{45} &= S_{4C} \\ a_1 S_{51} + a_2 S_{52} + a_3 S_{53} + a_4 S_{54} + a_5 S_{55} &= S_{5C} \quad \dots\dots(12) \end{aligned}$$

【0057】

定数項a0は式(9)を用いて求める。以上で求めたai (i=0、1、2、3、4、5)は装置製造時にR O Mに格納されている。装置による実際の測定では、測定値から求めた正規化パラメータX1～X5を回帰式(6)に代入することで、グルコース濃度Cが算出される。

【0058】

次にグルコース濃度の算出過程の具体例を示す。予め健常者および糖尿病患者に対して測定した多数のデータから式(6)の係数が決められており、マイクロプロセッサのR O Mには下記のグルコース濃度の算出式が格納されている。

【0059】

【数12】

$$C = 105.0 - 20.0X_1 + 38.5X_2 - 78.9X_3 - 15.2X_4 - 41.1X_5, \quad \dots\dots(13)$$

【0060】

X1～X5はパラメータx1～x5を正規化したものである。パラメータの分布が正規分布であると仮定すると、正規化パラメータの95%は-2～+2の間の値をとる。

【0061】

健常者の測定値の一例として、正規化パラメータX1=+0.10、X2=-0.02、X3=+0.04、X4=-0.20、X5=+0.20を上記の式に代入するとC=94mg/dlとなる。

【0062】

また、糖尿病患者の測定値の一例として、正規化パラメータX1=-1.10、X2=+0.10、X3=-0.84、X4=-1.04、X5=-0.20を上記の式に代入するとC=221mg/dlとなる。

【0063】

従来の測定方法である、採血によって得た血液を試薬と反応させ、この反応によって発生した電子量を測定して血糖値を測定する酵素電極法による測定結果と本発明の一実施例による測定結果について以下に述べる。健常者の測定値の一例として、酵素電極法によるグルコース濃度が89mg/dlのとき、同時刻に本法による測定から得た正規化パラメータX1=+0.10、X2=-0.02、X3=+0.04、X4=-0.20、X5=+0.20を上記の式に代入するとC=94mg/dlとなる。また、糖尿病患者の測定値の例として、酵素電極法によるグルコース

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濃度が238mg/dlのとき、同時刻に本法による測定から得た正規化パラメータ $X1=-1.10$ 、 $X2=+0.10$ 、 $X3=-0.84$ 、 $X4=-1.04$ 、 $X5=-0.20$ を上記の式に代入すると $C=221\text{mg/dl}$ となる。上記の結果より、本発明による方法によって、高精度でグルコース濃度を求められることが確認された。

【0064】

図11は、縦軸を本法によるグルコース濃度の算出値、横軸を酵素電極法によるグルコース濃度の測定値として、複数の患者に対してそれぞれの測定値をプロットした図である。本法の様に酸素供給量・血流量を測定することで良好な相関が得られる。

【0065】

図12に装置の操作手順を示す。操作部のボタンを押し装置の電源を入れると、液晶表示部に「ウォーミングアップ」が表示され、装置内の電子回路がウォーミングアップされる。同時に、チェックプログラムが作動し、電子回路を自動的にチェックする。「ウォーミングアップ」が終了すると、液晶表示部に「指を置いてください」と表示される。指置き部に指を置くと、液晶表示部にカウントダウンが表示される。カウントダウンが終了すると、液晶表示部に「指を離してください」と表示される。指置き部から指を離すと、液晶表示部に「データ処理中」が表示される。その後、液晶表示部に血糖値が表示される。この時点で、表示された血糖値は、日時・時間とともにICカードに記憶される。表示された血糖値を読み取ったら、操作部のボタンを押す。装置は、約1分後に次の測定を待つ「指を置いてください」が液晶表示部に表示された状態になる。

【0066】

なお、測定時間中は、常に温度T2を冷却しているのが望ましいが、電池で長時間駆動させる等の都合で、装置の省電力化が必要な場合は、図12で述べた操作手順に沿ってファン動作のオンオフ制御を行っても良い。図13にファン動作のシーケンスを示す。横軸が図12で述べた操作手順である。「開始」から「指を離して下さい」までは、ファンのオン動作が必要であるが、「指を離して下さい」から「結果表示」までは測定していないため、ファンをオフさせる。そして「結果表示」後、再び測定に入るまでにファンをオンさせ、温度T2を初期の状態に素早く戻す。こうすることで、ファン動作をオフさせる分、装置の省電力が図れる。

【図面の簡単な説明】

【0067】

【図1】本装置における血流量の測定原理を示す熱回路網の概略図。

【図2】各種センサによる測定値と、それから導出されるパラメータとの関係を図示した説明図。

【図3】無侵襲血糖値測定装置の上面図。

【図4】本発明の第一実施例を示す測定部の断面図。

【図5】温度T1、T2の温度上昇曲線を示す図。

【図6】本発明の第二実施例を示す測定部の断面図。

【図7】温度T1の温度上昇曲線を示す図。

【図8】本発明の第三実施例を示す測定部の断面図。

【図9】光学センサ部の断面図。

【図10】本発明によるグルコース濃度算出値および酵素電極法によるグルコース濃度測定値のプロット図。

【図11】装置内におけるデータ処理の流れを示す概念図。

【図12】装置の操作手順を示す図。

【図13】ファン動作のシーケンスを示す図。

【符号の説明】

【0068】

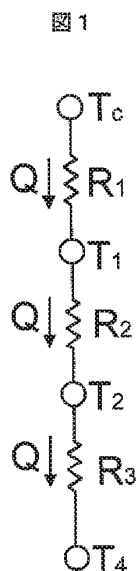
11…操作部、12…測定部、13…表示部、14…カバー、15…指置き部、16…輻射温度センサ部の開口端、17…接触温度センサ部、18…光学センサ部、20…指の腹、21…棒状部材、22…断熱材、23、24…サーミスタ、25…ダクト、26…筐体

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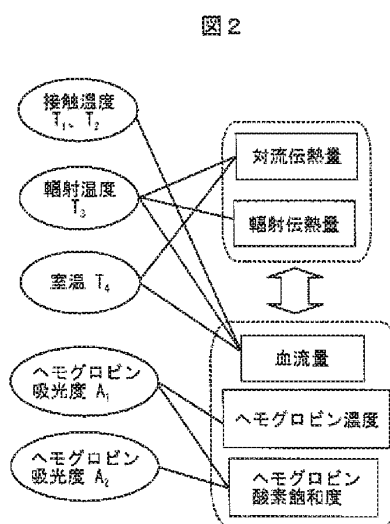
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、27…室温空気、28…ファン、29…赤外線レンズ、30…赤外線透過窓、31…焦電検出器、32…サーミスタ、40…冷却側ヒートシンク、41…ペルチェ素子、42…放熱側ヒートシンク、43…ヒートパイプ、44…フィン、45…ダクト、46…ファン、50…液冷ジャケット、51…ポンプ、52…ラジエータ、53…チューブ、60…光ファイバー、61…光ファイバー、62…発光ダイオード、63…発光ダイオード、64…フォトダイオード

【図1】



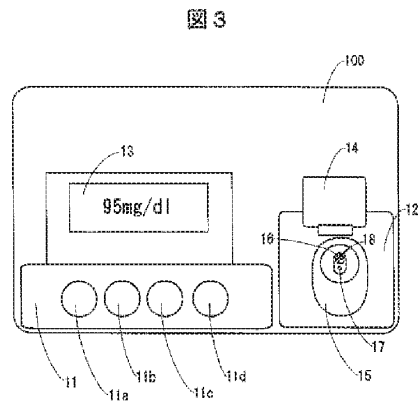
【図2】



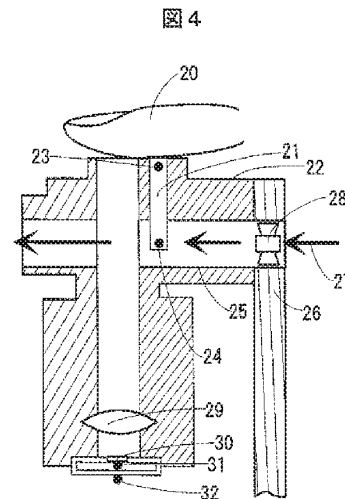
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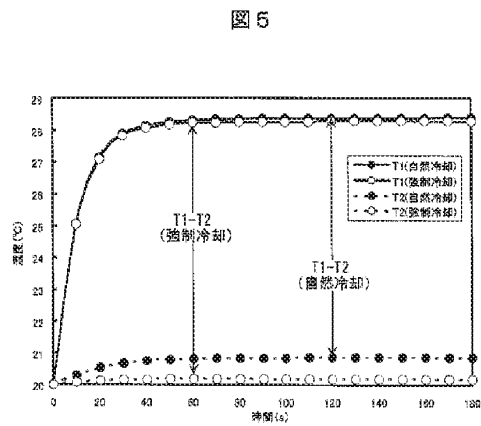
【図3】



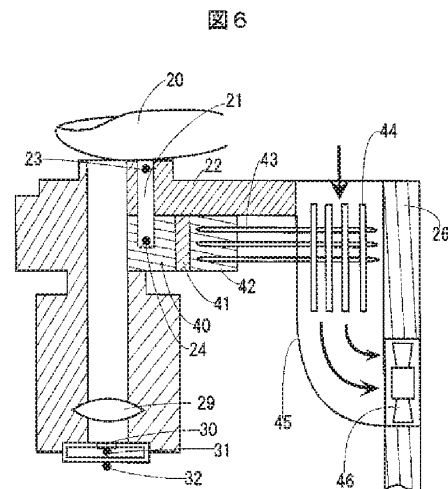
【図4】



【図5】



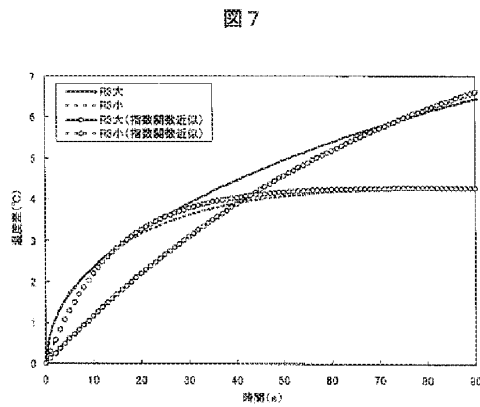
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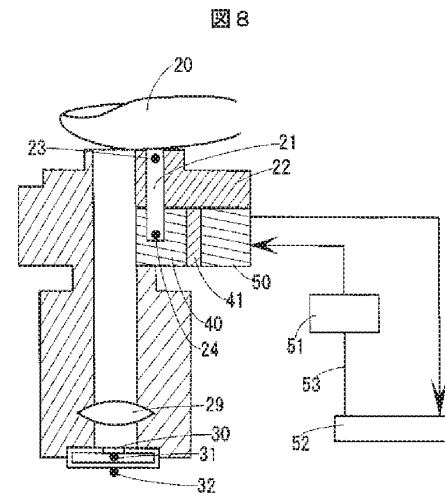
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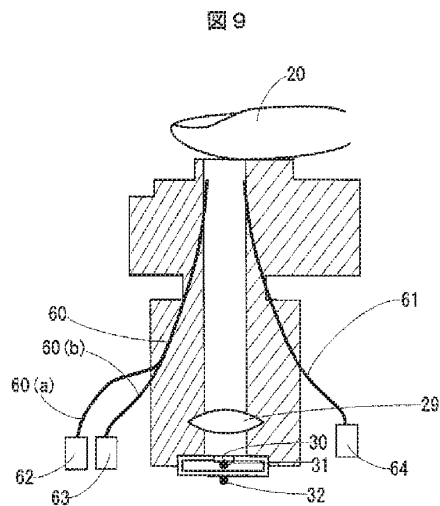
【図7】



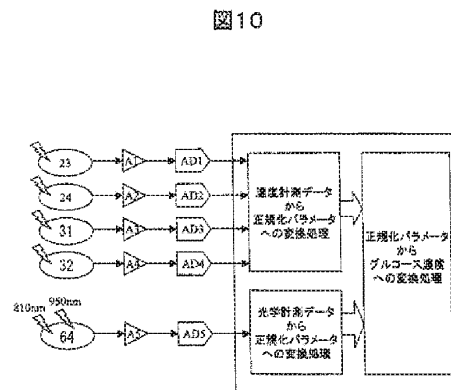
【図8】



【図9】



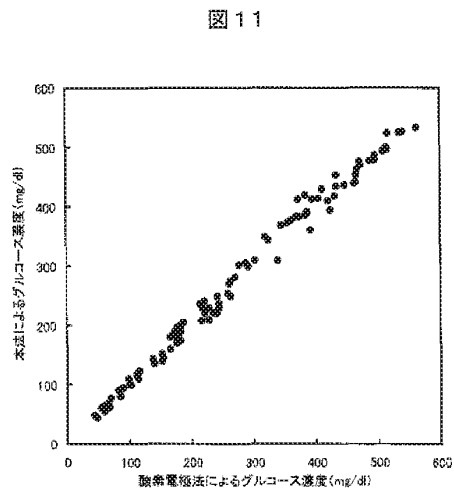
【図10】



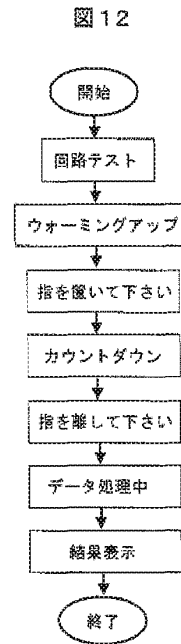
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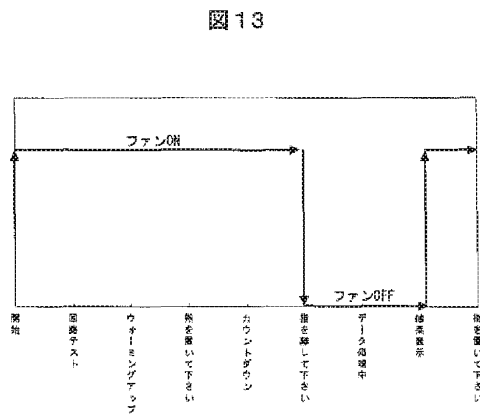
【図11】



【図12】



【図13】



(1 7)

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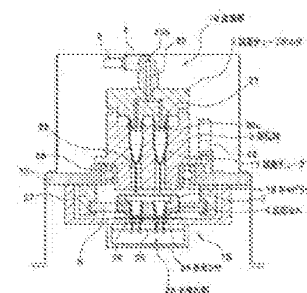
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 KAMAHORI MASAO

**(54)LUMINESCENCE DETECTION APPARATUS****(57)Abstract**

PROBLEM TO BE SOLVED: To provide a luminescence detection apparatus of a compact constitution capable of easily determining DNA base sequences at low costs.

SOLUTION: The luminescence detection apparatus 1 includes a plurality of reaction cells 6 having a transparent bottom part; liquid feeding parts 19 provided with capillaries 18 positioned above the reaction cells 6 and made to correspond in one-to-one to the reaction cells 19; and a photo-detection part 29 having a plurality of photo-detection elements 24 arranged closely to the lower surfaces of the reaction cells 6 and made to correspond in one-to-one to the reaction cells 6. By injecting a reagent solution from the liquid feeding part 19 to the reaction cells 6, luminescence generated in the reaction cells 6 is separately detected by the plurality of photo-detection elements 24 of the photo-detection part 29.

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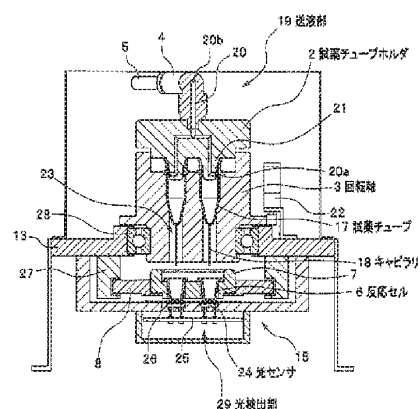
(54) 【発明の名称】 発光検出装置

(57) 【要約】

【課題】 小型の構成にて簡便かつ低コストで、DNA塩基配列を決定できる発光検出装置を提供する。

【解決手段】 透明な底部を有する複数の反応セル6と、反応セル6の上方に位置し、反応セルと一対一に対応付けられるキャピラリ18を備える送液部19と、反応セル6と一対一に対応して反応セル6の下面に近接して配列された複数の光検出素子24を有する光検出部29とを含み、送液部19から試薬溶液を反応セル6に注入することにより反応セル6内で発生する発光を光検出部29の複数の光検出素子24によって個別に検出することを特徴とする発光検出装置1である。

【選択図】 図4



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【特許請求の範囲】

【請求項1】

実質的に透明な底部を有する複数の反応セルと、前記反応セルの上方に位置し、前記反応セルと一対一に対応付けられるキャピラリを備える送液部と、前記反応セルと一対一に対応して前記反応セルの下面に近接して配列された複数の光検出素子を有する光検出部とを含み、前記送液部から試薬溶液を前記反応セルに注入することにより前記反応セル内で発生する発光を前記光検出部の光検出素子によって個別に検出することを特徴とする発光検出装置。

【請求項2】

実質的に透明な底部を有する4の倍数個の反応セルと、前記4の倍数個の反応セルの上方に位置し、前記4の倍数個の反応セルと一対一に対応付けられる4の倍数本のキャピラリを備える送液部と、前記4の倍数個の反応セルと一対一に対応して前記4の倍数個の反応セルの下面に近接して配列された複数の光検出素子を有する光検出部とを含み、前記送液部から試薬溶液を前記反応セルに注入することにより前記反応セル内で発生する発光を前記光検出部の光検出素子によって個別に検出することを特徴とする発光検出装置。

【請求項3】

実質的に透明な底部を有する複数の反応セルと、前記反応セルの上方に位置し、前記反応セルと一対一に対応付けられるキャピラリを備える送液部と、前記反応セルと一対一に対応して前記反応セルの下面に近接して配列された複数の光検出素子を有する光検出部とを含み、前記送液部から試薬溶液を前記反応セルに注入することにより前記反応セル内で発生する発光を前記光検出部の光検出素子によって個別に検出する発光検出装置であって、

前記送液部は、試薬溶液を入れる複数の試薬容器と、前記複数の試薬容器に連通する前記複数のキャピラリと、前記複数の試薬容器内を加圧する圧力源と、前記複数の試薬容器と前記圧力源を連通させる流路を含んでなり、

前記圧力源によって前記複数の試薬容器内を所定時間加圧する定圧加圧送液法によって、前記複数のキャピラリの吐出口から前記複数の反応セルに試薬溶液を均等に送液することを特徴とする発光検出装置。

【請求項4】

実質的に透明な底部を有する複数の反応セルと、前記反応セルの上方に位置し、前記反応セルと一対一に対応付けられるキャピラリを備える送液部と、前記反応セルと一対一に対応して前記反応セルの下面に近接して配列された複数の光検出素子を有する光検出部とを含み、前記送液部から試薬溶液を前記反応セルに注入することにより前記反応セル内で発生する発光を前記光検出部の光検出素子によって個別に検出する発光検出装置であって、

前記反応セルを、前記反応セルを保持している保持板を振動させることにより攪拌する攪拌手段と、

少なくとも前記反応セルと前記反応セルと一対一に対応する前記光検出素子との間に、前記反応セルから分離して、透明導電膜を備えたことを特徴とする発光検出装置。

【請求項5】

前記攪拌手段の攪拌周波数が、20Hz以上であることを特徴とする請求項4に記載の発光検出装置。

【請求項6】

前記反応セルと前記送液部は、相対的に回転する少なくとも二つの円板あるいは保持板上に配置され、前記円板あるいは前記保持板を回転させて、前記送液部から試薬溶液を前記反応セルに注入することを特徴とする請求項1に記載の発光検出装置。

【請求項7】

前記送液部と前記反応セルは、同一間隔で同一円周上に配置されていることを特徴とする請求項1に記載の発光検出装置。

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【請求項8】

前記反応セルと前記光検出部の複数の光検出素子との間にレンズまたは集光デバイスを配置したことを特徴とする請求項1に記載の発光検出装置。

【請求項9】

前記反応セルを一括して攪拌する攪拌手段を備えたことを特徴とする請求項1、請求項2、請求項3または請求項5に記載の発光検出装置。

【請求項10】

前記攪拌手段は、前記反応セルを保持している保持板を振動させることを特徴とする請求項9に記載の発光検出装置。

【請求項11】

前記攪拌手段は、前記反応セル中の磁気粒子を磁場生成手段により運動させることを特徴とする請求項9に記載の発光検出装置。

【請求項12】

前記送液部から注入される前記試薬溶液はデオキシリボヌクレオチド三リン酸、またはこれらの類似体核酸を含む溶液であることを特徴とする請求項1ないし請求項5のいずれか1項に記載の発光検出装置。

【請求項13】

注入される前記デオキシリボヌクレオチド三リン酸、またはこれらの類似体核酸を含む溶液に対応した送液部を備え、異なる前記反応セルに同時に注入することを特徴とする請求項12に記載の発光検出装置。

【請求項14】

4種類の異なるデオキシリボヌクレオチド三リン酸、またはこれらの類似体核酸を含む溶液が異なる4本の送液部に一対一に対応して、異なる前記反応セルに同時に注入することを特徴とする請求項12に記載の発光検出装置。

【請求項15】

前記送液部は、試薬溶液を入れる複数の試薬容器と、前記複数の試薬容器に連通する前記複数のキャピラリと、前記複数の試薬容器内を加圧する圧力源と、前記複数の試薬容器と前記圧力源を連通させる流路を含んでなり、

前記圧力源によって前記複数の試薬容器内を所定時間加圧する定圧加圧送液法によって、前記複数のキャピラリの吐出口から前記複数の反応セルに試薬溶液を均等に送液することを特徴とする請求項1、請求項2、請求項4または請求項5に記載の発光検出装置。

【請求項16】

前記光検出部の光検出側に透明導電膜が配置し、前記透明導電膜を接地されていることを特徴とする請求項1、請求項2、請求項3または請求項5に記載の発光検出装置。

【請求項17】

前記反応セルに核酸試料、前記核酸試料の一部の配列に相補的な配列を含むプライマー、DNAポリメラーゼ、ルシフェリンおよびルシフェラーゼのいずれか一つを含む溶液を保持し、前記反応セル内で、前記核酸試料に前記プライマーをハイブリダイズさせ、少なくとも1種の前記デオキシリボヌクレオチド三リン酸またはこれらの類似体と前記DNAポリメラーゼを用いた相補鎖伸長反応の進行により生成するピロリン酸をアデノシン5'-三リン酸(ATP)に変換し、前記ATP、前記ルシフェリンおよび前記ルシフェラーゼの反応により生成する生物発光を、前記光検出部の光検出素子で検出することを特徴とする請求項1ないし請求項5のいずれか1項に記載の発光検出装置。

【発明の詳細な説明】

【技術分野】

【0001】

本発明は、試薬溶液と反応溶液の生物・化学的反応によって放出される発光を検出する発光検出装置に関する。

【背景技術】

【0002】

従来、DNA塩基配列を自動決定するDNAシーケンサとして、ゲル電気泳動やキャピ

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ラリーアレイ電気泳動等の蛍光式DNAシーケンサが幅広く普及している。これらのDNAシーケンサを用いたDNA塩基配列決定方法は、ダイデオキシ(サンガー)法で調整したDNA断片を電気泳動にかける方式である(例えば、非特許文献1参照)。

特に、キャピラリーアレイ電気泳動は、一度に長い塩基配列を決定することができるために、2003年4月にヒトゲノムコンソーシアムにおいて完了宣言が出されたヒトゲノム解析においても大いに活躍した。

【0003】

ヒトゲノム解析の完了時期と前後して、DNAシーケンサに対する需要は、大規模シーケンス向けの高速・大量解析用の装置と、小型の構成にて簡便かつ低コストに使用できる装置とに分かれはじめている。

例えば、遺伝子診断や多型解析など、既知のゲノム情報との比較をおこなう場合には、新たにDNA全長を決定する必要はなく、目的とする短い範囲のDNA配列を決定すれば充分なことも多い。この場合、DNAシーケンサは小型の構成にて簡便かつ低コストな装置であることが好ましい。しかしながら、従来技術であるゲル電気泳動やキャピラリーアレイ電気泳動は、例えば、高圧電源を含んで構成する必要性等から、必ずしも適切であるとは言えない。

【0004】

そこで、前記要件を満たす方法として、ポリメラーゼによるDNA相補鎖伸長反応と生物発光検出法を組み合わせた段階的化学反应を用いたパイロシーケンス法(例えば、非特許文献2参照)と呼ばれるDNA塩基配列決定方法が注目を集めている。

【0005】

以下に、パイロシーケンス法の基本原理を示す。

パイロシーケンス法では、鋳型DNAに4種のdNTPを1種類ずつ順次加えてポリメラーゼによるDNA相補鎖伸長反応を行い、このDNA相補鎖伸長反応と並行して発光を検出することにより塩基配列決定を行う。

【0006】

パイロシーケンス法において、DNA相補鎖伸長反応が起こるとdNTPが取り込まれ、ピロリン酸が生じる。生じたピロリン酸をATPスルフィラーゼ等の酵素でATPに変換する。生じたATPをルシフェラーゼ/ルシフェリン反応系で発光させ、その生物発光を光学的に検出する。その際、どの種類のdNTPを加えたときに発光したかをモニタすることでDNA相補鎖伸長反応の有無がわかり、順次DNA塩基配列を決定できる。連続する塩基の場合には、DNA相補鎖伸長反応で生じるピロリン酸量が取り込まれる塩基数に比例、すなわち発光量に比例するため、発光強度をモニタすることによって、連続する同じ塩基種の数を決定できる。その際、加えたdNTPがいつまでも反応溶液に残留していると配列決定する上で障害となる。近年、dNTP分解酵素(アピラーゼ)を反応溶液中に共存させて余剰のdNTPを酵素分解する方式(特許文献1参照)が考案され、装置の自動化が実現されている。

このように、パイロシーケンス法においては、従来のゲル電気泳動やキャピラリーアレイ電気泳動で使用されていた、高圧電源、レーザ光源、DNAの分離スペース等、大きな構成部品を必要としない。

【特許文献1】特許第3533223号公報

【非特許文献1】T.A.Brown ゲノム メディカル・サイエンス・インターナショナル、2000年5月26日発行、p70-78

【非特許文献2】Anal. Biochem. 244, 367-373 (1997)

【発明の開示】

【発明が解決しようとする課題】

【0007】

前記したように、生物発光を活用するパイロシーケンス法は、ゲル電気泳動やキャピラリーアレイ電気泳動に比べ、小型の構成にて簡便かつ低コストでDNA塩基配列を決定できる方法として注目されている。

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しかしながら、パイロシーケンサの歴史は長くはなく、現在市販されているパイロシーケンサは、96穴タイタープレートを反応セルに用い、光学系にCCDカメラを使用した大型の装置(特表2002-518671号公報参照)であって、改善の余地がある。

また、簡便性やコスト面においても、改善の余地が残されている。

反応セルに注入する試薬溶液は少なくとも4種類(dATP、dCTP、dGTPまたはdTTPを含む)であり、通常は4本の試薬チューブと各試薬チューブに連通した4本のノズルとを1組にして試薬溶液を順次注入する。例えば、反応セルが96個の場合、すなわちタイタープレートを使用する場合には、4本の試薬チューブと各試薬チューブに連通した4本のノズルとのセットを96組、すなわち、384本の試薬チューブと各試薬チューブに連通した384本のノズルとを用意する必要がある。この場合、試薬チューブやノズルの本数が多く、製作コストが高くなることと、目詰まり等を防止するためのメンテナンスが煩雑になるという問題があった。

また、DNA塩基配列を決定する場合に加える試薬溶液、すなわちdNTP溶液量は、反応溶液量の1/100以下が望ましい。これは、加えるdNTP溶液量が多いと反応溶液量が増え、酵素濃度が低くなり反応速度が遅くなるためである。そのため、dNTP溶液を加える際には、反応溶液を攪拌する必要がある。このことは、特に、装置を小型化、あるいは注入する試薬溶液量を微量化する場合に重要となってくる。例えば、反応溶液量20 μ Lの場合には、dNTP溶液量は0.2 μ L以下であり、微量な反応溶液を効率よく攪拌する手段に加えて、微量な試薬溶液を精度よく注入する小型で簡便な手段が必要となる。

本発明は、前記した問題を解決し、小型の構成にて簡便かつ低コストで、DNA塩基配列を決定できる発光検出装置を提供することを目的とする。

【課題を解決するための手段】

【0008】

前記目的を達成するために、本発明は、実質的に透明な底部を有する複数の反応セルと、前記反応セルの上方に位置し、前記反応セルと一対一に対応付けられるキャピラリーを備える送液部と、前記反応セルと一対一に対応して前記反応セルの下面に近接して配列された複数の光検出素子を有する光検出部とを含み、前記送液部から試薬溶液を前記反応セルに注入することにより前記反応セル内で発生する発光を前記光検出部の複数の光検出素子によって個別に検出することの特徴とする発光検出装置である。

【0009】

このような構成とすることにより、送液部に備えられた全てのキャピラリーから試薬溶液を吐出させる構成となり、複雑な駆動部を用いない簡単な装置構成で、一括同時注入を実現でき、さらに、従来技術に比べ試薬チューブやキャピラリーの数を少なく構成することができる。また、全てのキャピラリーから所定時間毎に試薬溶液が吐出されるため、キャピラリー吐出口の乾燥などを考慮に入れて装置を設計する必要がない。

また、光検出部においては、大きな受光立体角を確保して複雑な光学系を使用せずに高集光効率で発光を検出できるため、簡便に高感度化が達成できる。

【発明の効果】

【0010】

本発明によれば、小型の構成にて簡便かつ低コストで、DNA塩基配列を決定できる発光検出装置を提供することができる。

【発明を実施するための最良の形態】

【0011】

以下、本発明の発光検出装置を実施するための最良の形態(以下「実施形態」と言う)について、適宜図面を参照しながら詳細に説明する。なお、以下の説明において、同一の構成要素には同一番号を付し、重複する説明は省略する。

【0012】

まず、図1および図2を用いて、本実施形態にかかる発光検出装置の概略を説明する。

図1は、発光検出装置1の外観斜視図であって、図2は、図1から本体カバー9を取り

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除いた発光検出装置1の要部を示す斜視図である。

図1に示すように、発光検出装置1の中央上部には、試薬チューブホルダ2と、試薬チューブホルダ2が着脱自在に固定される回転軸3とが配設されている。試薬溶液が入った試薬チューブ17は、回転軸3から試薬チューブホルダ2を取り外すことによって、試薬チューブホルダ2の下面に装着される(図3参照)。試薬チューブホルダ2の上部には、圧力配管4が回転シール5を介して接続されている。

【0013】

反応セル6は、試薬チューブ17と連通したキャピラリ18(図3参照)から吐出される試薬溶液と、あらかじめ反応セル6内に分注されていた反応溶液との反応の場である。本実施形態においては、例えば、DNA相補鎖伸長反応の場であると同時に、ルシフェリノーシフェラーゼ発光反応の場である。

なお、本実施形態において「試料」とは、分析の対象となる物質であって、生体試料に限定されない。また、生体試料においても、核酸に限定されない。また、「反応溶液」とは、少なくとも試料を含み、さらに、注入される試薬溶液との反応や発光反応に必要な、緩衝溶液、化合物、酵素等を適宜含んでいるものとする。

【0014】

反応セル6は、出入自在なトレー8の中央に反応セルホルダ7を介して配設されており、装置移動時にはトレー8の収容にともなって、試薬チューブ17に連通するキャピラリ18の下部垂直方向にそれぞれ搬入される。また、反応セル6を取り出したり交換したりする場合には、トレー8を引き出すことで、反応セル6が装置外に搬出される。なお、トレー8は、ガイド27(図4参照)によって保持されており、トレー8の出入は、本体カバー9上に設置されたエジェクトボタン10により操作することができる。

【0015】

以下、本実施形態においては、トレー8が発光検出装置1内に収容された状態であって、4つの反応セル6は、試薬チューブ17に連通するキャピラリ18の下部垂直方向にそれぞれ位置しているものとする。さらに、試薬チューブホルダ2下面には試薬チューブ17が装着され、試薬チューブホルダ2は回転軸3に固定されているものとする。

【0016】

本体カバー9、扉11および遮光板12は、発光検出装置1内部を遮光するための遮光部材として機能する。また、扉11は、試薬溶液の交換や、回転軸3および後記する送液部19(図4参照)のメンテナンスのために適宜開扉される。

【0017】

図2に示すように、回転軸3は、ベース13の上部に、回転軸受28(図4参照)を介して水平方向に回転自在に保持されている。さらに、ベース13の上部には、回転軸3の周囲をコ字型に囲むシールド14が設けられ、迷光を防ぐと同時に電気的なノイズを防ぐ。

一方で、ベース13の下方には、反応セル6を保持したトレー8と、反応セル6内で生じた光を検出するための光センサ24(図4参照)を格納したシールドケース15が配設されている。

なお、ベース13はスタンド16により支持されている。

【0018】

次に、図3および図4を参照して、本実施形態にかかる発光検出装置1について、詳細に説明する。

【0019】

図3は、試薬チューブ17に連通したキャピラリ18と、反応セル6との対応関係を説明するための図である。

なお、試薬チューブ17、キャピラリ18および反応セル6に関し、それぞれの対応関係を説明するために構成要素ごとに示す場合には、例えば、試薬チューブであれば、17a、17b、17c、17d等、末尾にアルファベットを付した符号により説明するが、構成要素全体を示す場合には、試薬チューブ17のように示して説明する。

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【0020】

4本の試薬チューブ17a-17dには、試薬溶液として、異なる4種のデオキシヌクレオチド溶液(dATP、dCTP、dGTPまたはdTTPを含む)またはその誘導体が1種類ずつ入り、各試薬チューブ17a-17dに連通した4本のキャピラリー18a-18dからそれぞれの試薬溶液が、圧力配管4から供給される空気圧により吐出される。各キャピラリー18a-18dのそれぞれの下部垂直方向には、各キャピラリー18a-18dと一対一に対応付けられる4つの反応セル6a-6dが配設されており、キャピラリー18a-18dから吐出される試薬溶液は、それぞれの下部垂直方向にある反応セル6a-6d内に注入される。

【0021】

図4は、図2で示した発光検出装置1の要部について、一点鎖線A-A'により垂直方向に切断し矢示方向から見た場合の縦断面図である。

送液部19は、試薬チューブ17と、試薬チューブ17と連通したキャピラリー18と、試薬チューブホルダ2内に形成されたガス流路20と、回転シール5と、圧力配管4と、図示しない圧力源とによって構成される。

【0022】

試薬チューブホルダ2の下面には、試薬チューブ開口部を密嵌するための4つの凸部21が形成されている。さらに、密嵌後の状態において、試薬チューブ内壁と着接していない各凸部21の突端側には、ガス流路20の下端であるガス供給口20aが形成されている。ガス供給口20aの数、すなわち、試薬チューブホルダ2に装着される試薬チューブ17の数に応じて、ガス流路20は試薬チューブホルダ2内で分岐している。なお、反応溶液の飛散防止のために、ガス供給口20aはガスが反応溶液液面に直接噴出されない角度で設けることが好ましい。

ガス流路20の上端20bは、回転シール5を介して圧力配管4と接続されており、ガス流路20は試薬チューブ17と圧力配管4とを連通させている。圧力配管4は、電磁弁等の圧力切り替え装置(図示せず)を介して3気圧(0.3MPa・G)以上の高圧ポンプやコンプレッサ等の圧力源(図示せず)に接続されている。なお、回転シール5は回転軸3の中央に配設されており、回転軸3が回転しても圧力配管4がねじれることはない。

【0023】

試薬チューブ17中の試薬溶液の反応セル6への送液には、定圧加圧送液法が好適である。

定圧加圧送液法は、圧力源からの圧縮空気(1~2気圧(0.1~0.2MPa・G)程度)を使用して、電磁弁等の圧力切り替え装置により数秒程度の空気圧を加えることにより行うものである。

圧力源から圧力配管4を介して送られる圧力は、複数の試薬チューブ17全てに均等に送られるので、1度のガス供給作業によって全部の試薬チューブ17から同時に試薬溶液を吐出させることができる。このような構成とすることにより、発光検出装置1を簡略化することができる。

なお、本実施形態で使用する定圧加圧送液法による試薬チューブ17の吐出量は、次のHagen-Poiseuilleの(1)式に従う。

【0024】

$$Q = \Delta P \cdot \pi \cdot r^4 \cdot t / (8 \mu L) \cdots (1)$$

(1)式において、 ΔP :加えた圧力、 r :微小細管の内径、 t :圧力を加えた時間、 μ :溶液の粘性、 L :微小細管の長さである。

(1)式で示すように、定圧加圧送液法においては、キャピラリー(微小細管)18は流量制御用部材であって、内径や長さの異なるキャピラリー18を選択することによって、流量を調節することができる。

例えば、大気圧程度(2気圧(0.2MPa・G)以下)の低圧使用、加圧時間2秒以下および吐出量0.2 μ L以下、の条件を満たすためには、内径25 μ m、長さ20mmのキャピラリー18を使用することが好適である。

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【0025】

回転軸3は、回転モータ22を駆動力として回転する。さらに、前記したように、回転軸3の上部には試薬チューブホルダ2が固定されているため、回転軸3の回転にともなうて、試薬チューブホルダ2と試薬チューブホルダ2に装着された試薬チューブ17も回転する。

また、回転軸3の内部には、試薬チューブホルダ2に装着した4本の試薬チューブ17を収容するために、軸方向に4つの貫通孔23が形成されている。

なお、回転モータ22は図示しないモータ制御手段によって制御することができる。例えば、モータ制御手段は、回転角と回転の時間間隔等を規定したプログラムを実装した制御部(CPU)であってもよい。4本のキャピラリ18と4つの反応セル6を備えてなる本実施形態においては、キャピラリ18と反応セル6を、所定時間毎に90°ずつ回転させるプログラム制御が好適である。あるいは、時間間隔の代わりに、検出される発光強度が所定値以下まで減衰する毎に、所定角度ずつ回転させるように規定したプログラムであってもよい。

【0026】

反応セル6の底部は透明な部材からなり、反応セル6は、反応セルホルダ7内に円周状に形成された貫通孔に上方から嵌入される。その結果、反応セル6内で生じた光を、反応セル6の底部より下方で検出することができる構成となっている。なお、反応セル6の底部は、実質的に透明であればよく、必ずしも全ての波長の光を透過させる必要はない。少なくとも、反応セル6の底部は、検出を所望する波長の光を透過させることができればよい。また、必ずしも100%の効率で光を透過させる必要はなく、正確な光の透過率が分かっているれば、測定後に、この透過率に基づいて測定値を補正すればよい。

【0027】

光検出部29は、少なくとも、光センサ24と、光センサ24の検出信号を増幅するために電氣的に接続されたアンプ25とを含んで構成され、ベース13に固定されたシールドケース15に格納されている。

光センサ24は、反応セル6の下部垂直方向に、反応セル6と一対一に対応付けられて配設されている。光センサ24を反応セル6毎に配設したことで、反応セル6の間隔、配設およびサイズに関係なく高感度で光を検出することができる。なお、アンプ25は、アンプ25毎に生じる出力誤差を考慮し、1個のアンプ25に対して4個の光センサ24を接続する構成を適用しているが、必ずしもこの構成に限定されない。

本実施形態では、レンズ等を使用した複雑な光学系を使用せず、簡便な方式で集光効率を高めるために、光センサ24を反応セル6に可能な限り近づけて受光角を大きくする密着型とし、部品数低減と光軸調整不要な簡単な構造で高集光効率が達成可能な構成としている。ただし、装置の構成によっては、反応セル6と光センサ24との間に、適宜レンズや集光デバイス等を配置することを妨げるものではない。

【0028】

前記したように、本実施形態では反応セル6に光センサ24が近接し、高倍率のアンプ25を使用しているため、静電誘導によるノイズ(微小漏れ電流)を検出してしまう問題がある。このノイズは、試薬溶液の注入時、または、後記する攪拌にともなう反応セルホルダ7またはトレー8の振動時に検出されやすい。

このノイズを除去するために、本実施形態では、反応セル6と、この反応セル6に対応する光センサ24との間に、透明導電膜26aを備えた構成としている。

【0029】

図5(a)は、本実施形態の透明導電膜26aの設置形態を説明するための要部拡大断面図である。

図5(a)に示すように、光センサ24の上部垂直方向を含むシールドケース15上面に、光透過性および化学的安定性に優れた石英ガラス板26を配設し、石英ガラス板26の下面をITO(酸化インジウム)またはSnO₂からなる透明導電膜26aでコーティングする構成としている。このように、透明導電膜26aを反応セル6に固着させるので

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はなく、反応セル6から分離して構成することで、反応セル6にかかるコストを低減させることができ、使い捨て可能な反応セル6を提供することができる。なお、透明導電膜26aはシールドケース15に面して接地しており、導電性接着剤等によりシールドケース15に貼着されている。

【0030】

なお、本実施形態においては、透明導電膜26aを反応セル6から分離して構成したが、この構成には限定されない。例えば、透明導電膜26aを反応セル6と一体に形成してもよい。

ここで、図5(b)は、通常の透明導電膜26aの設置形態を適用した場合を説明するための要部拡大断面図である。本実施形態においても、図5(a)のような分離した構成としない場合には、例えば、図5(b)に示すように、反応セル6の底部部材として石英ガラス板26を適用し、石英ガラス板26下面をITOまたは SnO_2 からなる透明導電膜26aでコーティングする構成とすることができる。

【0031】

本実施形態において、1度に反応セル6に注入される試薬溶液量は、あらかじめ反応セル6内に分注されていた反応溶液の約1/100であって、相対的に少量である。従って、反応による発光強度を適切に検出するためには、試薬溶液の自然拡散を待つのではなく、試薬溶液注入後に速やかに反応セル6を攪拌することが好適である。

【0032】

一つの攪拌手段として、例えば、振動モータを挙げることができる。

振動モータ(図示せず)は、反応セル6を保持する反応セルホルダ7、あるいは、反応セルホルダ7を保持するトレイ8に設置されている。反応セルホルダ7あるいはトレイ8を振動モータと接触・振動させることによって、全ての反応セル6を一括攪拌することができる。なお、振動モータには、例えば、携帯電話等に使用する小型の振動モータが利用できる。

【0033】

その他の攪拌手段として、例えば、磁気粒子等を挙げることができる。

具体的には、反応セル6内に磁気粒子等を添加し、反応セル6外に設けられた磁場生成手段(図示せず)によって反応セル6内に磁場をかけることで磁気粒子等を運動させて反応溶液を攪拌する。なお、この場合には、注入後数秒の攪拌を行えばよい。

【0034】

ただし、反応セル6を振動モータにより攪拌する場合には、振動にともなって、透明導電膜26aがシールドケース15と離間して接地が取れなくなる場合を考慮する必要がある。そこで、前記した透明導電膜26aの各設置形態について、振動モータによる攪拌の影響を実験例を参照しながら説明する。

なお、磁気粒子による攪拌は、反応セル6の振動が起らないので、前記した問題は考慮に入れなくてもよい。

【0035】

〔実験例1〕

実験例1においては、図5(a)で示した本実施形態の透明導電膜26aの設置形態と、図5(b)で示した通常の透明導電膜26aの設置形態を適用した場合について、振動モータによる攪拌の影響を示すための実験を行っている。

【0036】

〔検出条件〕

実験例1で使用した透明導電膜26aをコーティングした石英ガラス板26の性能は、波長450～600nmにおいて透過率90%以上、面積抵抗1000～1500Ωである。光センサ24には、浜松ホトニクス製ホトダイオードS1133-01を使用し、光センサ24の出力は、電流電圧変換増幅アンプ(BURR BROWN製OPA129UB)および10GΩの抵抗を用いて、 1×10^{10} に増幅し、2段目のオペアンプ(ANALOG DEVICES製OP07)を用いてトータルゲイン 1.8×10^{11} に増幅した。

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なお、実験例1はノイズを検出するための測定であるため、試薬溶液や反応溶液等は使用していない。

【0037】

〔実験結果〕

本実施形態の透明導電膜26aの設置形態(図5(a)参照)におけるノイズ測定結果を図7(a)に、通常の透明導電膜26aの設置形態を適用した場合(図5(b)参照)におけるノイズ測定結果を図7(b)に示す。図7(a)および図7(b)ともに、ノイズは検出されない。すなわち、両者ともに振動による攪拌を行っていない場合であるため、透明導電膜26aはシールドケース15に接地されており、透明導電膜26aのノイズ遮断機能は有効に機能している。

【0038】

図6(a)は、本実施形態の透明導電膜26aの設置形態(図5(a)参照)において、振動モータにより攪拌している状態を説明するための模式図であり、攪拌時のノイズ測定結果を図7(c)に示す。図7(c)において、ノイズは検出されない。振動モータにより、振動攪拌の際に反応セル6が上下に動いても、透明導電膜26aはシールドケース15に貼着されているため、透明導電膜26aのノイズ遮断機能は有効に機能している。

【0039】

図6(b)は、通常の透明導電膜26aの設置形態を適用した場合(図5(b)参照)において、振動モータにより攪拌している状態を説明するための模式図であり、攪拌時のノイズ測定結果を図7(d)に示す。図7(d)において、ノイズが検出された(時間15秒において、 -0.04V 程度の信号強度を検出したことを示す)。振動攪拌による反応セルの上下動のために、反応セル底部に形成された透明導電膜はシールドケース15と離間して接地がとれなくなるためである。

従って、実験例1の結果によれば、攪拌手段として振動モータを用いる場合には、本実施形態の透明導電膜26aの設置形態(図5(a)参照)が好適であることが示された。

【0040】

〔実験例2〕

実験例2においては、振動モータによる攪拌の至適条件を検討するための実験を行っている。

【0041】

〔検出条件〕

反応に用いた反応溶液は $20\mu\text{L}$ であり、試薬溶液(デオキシヌクレオチド溶液)を $0.2\mu\text{L}$ 注入した。未反応の試料DNA(鋳型DNA)の量は、同一試薬溶液(デオキシヌクレオチド溶液)を再度注入し、反応した量とした。試薬溶液および反応溶液の組成については、後記する実施例「表1」を参照する。

装置等の設定は、実験例1の検出条件に従った。

【0042】

〔実験結果〕

図8は、振動モータの振動数と未反応DNA鎖の割合との相関関係を示している。

振動モータの攪拌周波数が 20Hz 以上で未反応物の割合が、数%以下になった。特に、攪拌周波数 25Hz 以上では、未反応物の割合はほぼ0%で、完全に反応が進んでいることが分かる。図示を省略したが、さらに、攪拌周波数を大きくすると反応セル6が振動しなくなり、逆に反応効率が低下する。 100Hz 以上では10%以上の未反応が起こる。

【0043】

なお、以上説明した本発明は、その技術思想のおよぶ範囲で、種々の変更実施を行うことができる。例えば、本実施形態においては、反応セル6は移動せず、キャピラリー18が回転する構成を示したが、キャピラリー18を移動させずに反応セル6を回転させる構成としてもよい。

【0044】

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また、本実施形態では反応セルの数を塩基の種類に対応して4つとして説明したが、8個、12個、16個等、4の倍数個の反応セルを設けてもよい。さらに、増加させた反応セルの数に対応させて試薬チューブの数を適宜増加させてもよい。以下、反応セルの数に関する変形例を、適宜図面を参照して説明する。

【0045】

図9は、反応セルの数に関する変形例1を示す図である。

変形例1においては、4つの反応セル106a-106dに加え、それぞれの反応セル106a-106dの外周方向にさらに4つの反応セル106e-106hを設けた構成である。また、各反応セル106a-106hの上部垂直方向には試薬チューブ117a-117hに連通したキャピラリ118a-118hを配設している。なお、変形例1においては、試薬チューブ117a-117dと試薬チューブ117e-117hそれぞれについて、異なる4種のデオキシヌクレオチド溶液(dATP、dCTP、dGTPまたはdTTPを含む)またはその誘導体が1種類ずつ入っている。

このような構成とすることで、回転軸3の数を増加させることなく反応セル6の数を増加させることができ、一度に分析できる試料数を増やすことができる。

【0046】

図10は、反応セルの数に関する変形例2を示す図である。

図10に示すように、半径方向に隣接するキャピラリ(例えば、218aと218e)が、同一の試薬溶液を吐出する場合、1本の試薬チューブ217につき、複数本のキャピラリ218を連通させる構成としてもよい。このような構成とすることで、試薬チューブ217の数を減らすことができるため、試薬溶液の交換を簡易に行うことができる。

【0047】

図11は、反応セルの数に関する変形例3を示す図である。

変形例3は、4の倍数個の反応セル306a-306hが、円周上に等間隔に配設されている場合である。また、各反応セル306a-306hの上部垂直方向には試薬チューブ317a-317hに連通したキャピラリ318a-318hを配設している。この場合、例えば、318a、318b、318c、318d、318e、318f、318g、318hの順に、それぞれ、dATP、dGTP、dCTP、dTTP、dATP、dGTP、dCTP、dTTPを含む試薬溶液を吐出させるように配列させ、45°ずつ回転させればよい。このような構成とすることで、回転軸3や送液部19の数を増加させることなく反応セル6の数および試薬チューブ17の数を増加させることができる。また、前記した実施形態の回転角が90°であったのに比べ、回転軸3を駆動させる回転モータ22の作業を減少させることができる。

【0048】

また、図示していないが、反応セルの数に関する変形例4として、縦8穴×横12穴の96穴マイクロプレート反応セル6として適用する場合について説明する。96穴マイクロプレート中の互いに隣接する縦2穴×横2穴の計4つのウェル毎に、順次、図3で示した1つの送液部19、すなわち、4本のキャピラリ18をそれぞれ上部垂直方向に配設する構成とすることができる。このような構成とすることで、多くとも24個の送液部19、すなわち、96本の試薬チューブ17と、各試薬チューブ17に連通した96本のキャピラリ18によって、96試料を同時に分析することができる。

なお、市販のマイクロタイクプレート反応セル6として適用する場合には、隣接するウェル(反応セル)同士の発光のクロストークを防止するために、反応セルホルダ7にクロストーク防止用の仕切りを設けることが好ましい。

【0049】

また、反応セル6の数がキャピラリ18の数よりも多い場合には、送液部19にアクチュエータを設け、4つの反応セル6の分析完了毎に、次の4つの反応セル6に送液部19を移動させる構成としてもよい。

【実施例】

【0050】

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次に、本発明の発光検出装置1の効果を確認した実施例をDNA塩基配列決定方法を例にさらに詳細に説明する。

なお、本実施例は、図3で示したように、本実施形態の構成である4つの反応セル6と4種のdNTPに対応した4つの試薬チューブ17を備えた発光検出装置1によって塩基配列の決定を行った。従って、本実施例における、反応セル6、試薬チューブ17およびキャピラリー18の対応関係は、図3を参照して説明する。

【0051】

本実施例で使用した透明導電膜26aをコーティングした石英ガラス板26の性能は、波長450～600nmにおいて透過率90%以上、面積抵抗1000～1500Ωである。光センサ24には、浜松ホトニクス製ホトダイオードS1133-01を使用し、光センサ24の出力は、電流電圧変換増幅アンプ(BURR BROWN製OPA129UB)および10GΩの抵抗を用いて、 1×10^{10} に増幅し、2段目のオペアンプ(ANALOG DEVICES製OP07)を用いてトータルゲイン 1.8×10^{11} に増幅した。

【0052】

本装置で行うDNA塩基配列決定方法の原理は、DNAに相補鎖結合したプライマーの伸長反応時に生成するピロリン酸(PPi)をルシフェリン/ルシフェラーゼ系の生物発光反応法で検出するものである。以下に、反応スキームを説明する。

【0053】

測定対象の試料DNAに伸長反応用プライマーをハイブリダイズさせる。試料DNAと伸長反応用プライマーがハイブリダイズした状態にDNAポリメラーゼを用いてDNA相補鎖伸長反応を行う。その際、試薬溶液としてデオキシリボヌクレオチド三リン酸(あるいは類似対核酸)溶液を1種類ずつ、順次加えていくと、DNA相補鎖伸長反応が起きた場合のみ、PPiが生じる。DNA相補鎖伸長反応により生じたPPiは、APS(アデノシン5'-ホスホスルフェイト)存在下でATPスルフィラーゼにより、 SO_4^{2-} (硫酸イオン)を生じて、ATPに変換される。ATPスルフィラーゼにより変換されたATPは、マグネシウムイオンおよび O_2 (酸素)存在下でルシフェラーゼによるルシフェリンの酸化反応に使用され、光を発する。その際、 CO_2 (炭酸ガス)が生じると共に、ATPはPPiとAMPに、ルシフェリンはオキシルシフェリンに変換される。ルシフェリン/ルシフェラーゼ系の生物発光に伴い生じたPPiは、再度APS存在下でATPスルフィラーゼにより、ATPに変換され、発光反応が繰り返し起こり、発光は持続する。本DNA塩基配列決定方法は、dNTP溶液を順番に繰り返し加え、発光の有無を検出しながら1個ずつ塩基配列を決定していく方法(Ahmadian, Aら, Analytical Biochemistry 280 (2000) 103-110 およびZhou, Gら, Electrophoresis 22 (2001) 3497-3504参照)であり、本発明の発光検出装置1を用いて容易に行うことができる。

以下、本実施例の具体的な測定方法を説明する。

【0054】

本実施例では、試料DNAとして以下に示す遺伝子(thiopurine S-methyltransferase gene)、および、この配列の3'端と相補的な配列であるシーケンシング用プライマーを使用した。

【0055】

```
thiopurine S-methyltransferase gene
5' -tgttggaagtaccagcatgcacatggggacgctgctcatcttcttaagatttgattttctccataa
aatgtttttctctcttcttgtaggacaaatattggcaaatggacatgattgggatagaggacattagttgca
ttaatccagtgatcgcaaatgtaagtaatttt-3'
シーケンシング用プライマー
5' -aaaattacttaccatttgcgacga-3'
```

【0056】

本実施例で使用した試薬溶液および反応溶液の組成を「表1」に示す。

なお、ここで使用した試薬溶液および反応溶液の組成や濃度は、測定法の一例であり、装置構成や試料DNA等に応じて適宜変更できる。

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【0057】

【表1】

各溶液の試薬組成

試薬溶液	dNTP (300 μ M dATP α S, 200 μ M CTP, 200 μ M dGTP, or 200 μ M dTTP) 5.0 μ M APS 10 mM Tris-acetate buffer, pH7.75
反応溶液	Sample DNA 0.1 M Tris-acetate buffer, pH7.75 0.5 mM EDTA 5.0 mM magnesium acetate 0.1 % (v/v) bovine serum albumin 1.0 mM dithiothreitol 0.1 U/ μ l DNA polymerase I, Exo-klenow Fragment 1.0 U/ml ATP sulfurylase 2.0 mg/ml luciferase 20 mM D-luciferin

【0058】

各反応セル6には、反応溶液を合計31 μ L分注し（うち、1 μ Lはプライマーアニーリング処理が施された試料DNAであり、測定直前に添加している）、この反応溶液に、試薬溶液（デオキシヌクレオチド溶液）0.3 μ Lを順次注入して、発光反応を測定した。

ここで、プライマーアニーリング処理が施された試料DNAとは、試料DNA（400 fmol）と1.5倍量のシーケンシング用プライマーをアニーリングバッファー中（10 mM Tris-acetate buffer, pH7.75, 2 mM magnesium acetate）でハイブリダイゼーション（95℃、20秒→60℃、120秒→室温）を行ったものである。ただし、試料DNAとシーケンシング用プライマーとのハイブリダイゼーションの方法は、前記したものに限定されない。例えば、反応セル6に試料DNAとシーケンシング用プライマーを添加した後に、ハイブリダイゼーションに必要な所定の温度操作を行ってもよい。

なお、本実施例においては、4つの反応セル6内に同一の試料DNAを含む同一の反応溶液を分注している。

【0059】

試薬チューブ17a、試薬チューブ17b、試薬チューブ17cおよび試薬チューブ17dには、試薬溶液として、それぞれdATP α S溶液、dGTP溶液、dTTP溶液およびdCTP溶液が保持されている。また、各試薬溶液には、APSが含まれている（「表1」参照）。

なお、本実施例においては、dATPの代わりに、類似体であるdATP α Sを使用している。dATP α Sは、dATP同様に、DNA相補鎖伸長反応の際にDNA 3' 端に付加しピロリン酸を放出する基質として機能する一方で、ルシフェラーゼに対する基質特異性、すなわち基質としての働きはdATPの場合の2桁以下であるため、dATPを使用した場合に比べてバックグラウンドノイズの大きさが非常に小さくなる。従って、試薬溶液としてdATPの代わりにdATP α Sを使用することにより、感度が向上するため、より好ましい。

【0060】

測定開始直後には、反応セル6a、反応セル6b、反応セル6cおよび反応セル6dの

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上部には、それぞれ、試薬チューブ17a、試薬チューブ17b、試薬チューブ17cおよび試薬チューブ17dが配設されている。

【0061】

DNA塩基配列の決定は、4つの反応セル6中の反応溶液に同時にdNTP溶液を注入し、所定時間後試薬チューブ17を反時計回りに90°回転し、次のdNTP溶液を同時に注入して行う。

ここで、図12を参照して、本実施例において、各反応セル6に注入されるdNTP溶液の順番を示す。なお、前記したように本実施例においては、dATPの代わりにdATPαSを使用しているが、4種dNTPの関係を簡潔に示すために、図中ではdATPと示す。

試薬溶液注入の時間間隔は、30〜90秒である。通常は反応の進行を確実にするために1反応1分とし、1塩基配列決定に4分要するが、試薬溶液および反応溶液の組成ならびに試料DNAの塩基配列によって適宜変更される。

【0062】

図13は、本実施例における各反応セル6の発光検出データである。図13(a)、(b)、(c)および(d)のDNA塩基配列データは、それぞれ、図12に示す反応セル6a、反応セル6b、反応セル6cおよび反応セル6dに対応している。全ての反応セル6において、重複するDNA塩基配列データを得た。なお、本実施例においては、前記したように、4つの反応セル6において、同一の試料DNAの塩基配列を分析している。

本実施例の結果から、本発明にかかる発光検出装置1を使用することで、全ての反応セル6において同時かつ適切にDNA塩基配列を決定することができることを示した。

【産業上の利用可能性】

【0063】

ここで開示した装置は簡便なDNAシーケンサとして、さらには一塩基伸長反応等のDNA検査装置として大きく産業分野に活用される。さらに、ATP測定による細菌検査、あるいは小型ルミノメータとしても活用できる。

【図面の簡単な説明】

【0064】

【図1】本発明の一実施形態である発光検出装置の外観斜視図である。

【図2】図1に示す発光検出装置から本体カバーを取り除いたときの発光検出装置の要部を示す斜視図である。

【図3】本発明の一実施形態である送液部と反応セルとの対応関係を説明するための図である。

【図4】本発明の一実施形態である発光検出装置の要部の縦断面図である。

【図5】透明導電膜の設置形態を説明するための要部拡大断面図であって、(a)は、本実施形態の透明導電膜26aの設置形態であり、(b)は、通常の透明導電膜の設置形態を適用した場合である。

【図6】図5に示した透明導電膜の設置形態において、振動モータにより攪拌している状態を説明するための模式図であって、(a)は、本実施形態の透明導電膜の設置形態、(b)は、通常の透明導電膜の設置形態を適用した場合について、それぞれの攪拌時の構成を示す。

【図7】本実施形態および通常の透明導電膜の設置形態において、それぞれ、非攪拌時と攪拌時のノイズの検出結果である。

【図8】振動モータの振動数と反応効率の相関関係を示す測定データである。

【図9】反応セルの数に関する変形例1である送液部と反応セルとの対応関係を説明するための図である。

【図10】反応セルの数に関する変形例2である送液部と反応セルとの対応関係を説明するための図である。

【図11】反応セルの数に関する変形例3である送液部と反応セルとの対応関係を説明するための図である。

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【図12】本実施例において各反応セル6に注入されるdNTP溶液の順番を説明するための図である。

【図13】本実施例における各反応セルの発光検出データである。

【符号の説明】

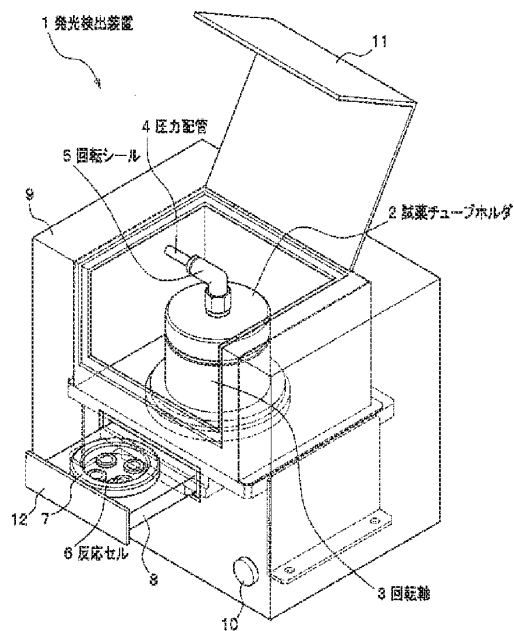
【0065】

- 1 発光検出装置
- 2 試薬チューブホルダ(円板)
- 3 回転軸
- 4 圧力配管(流路)
- 5 回転シール(流路)
- 6 反応セル
- 7 反応セルホルダ(保持板)
- 8 トレー(保持板)
- 9 本体カバー
- 10 エジェクトボタン
- 11 扉
- 12 遮光板
- 13 ベース
- 14 シールド
- 15 シールドケース
- 16 スタンド
- 17 試薬チューブ(試薬容器)
- 18 キャピラリ
- 19 送液部
- 20 ガス流路(流路)
- 20a ガス供給口
- 20b 上端
- 21 凸部
- 22 回転モータ
- 23 貫通孔
- 24 光センサ(光検出素子)
- 25 アンプ
- 26 石英ガラス
- 26a 透明導電膜
- 27 ガイド
- 28 回転軸受
- 29 光検出部

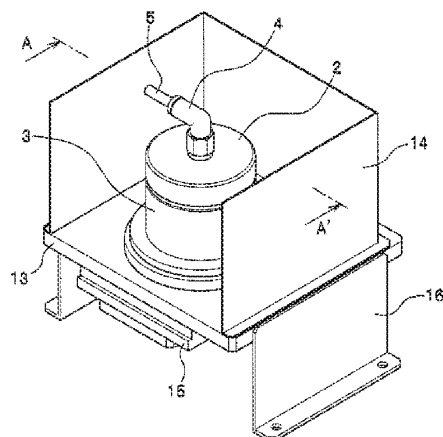
(16)

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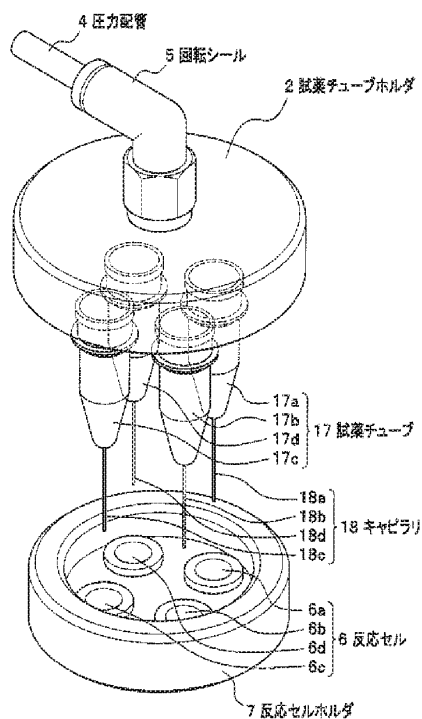
【図1】



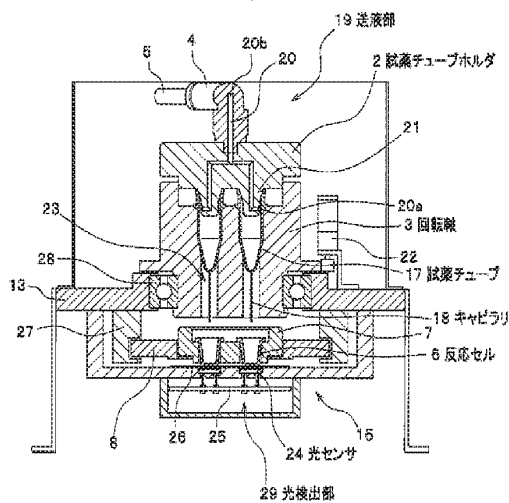
【图2】



【图3】



【图4】

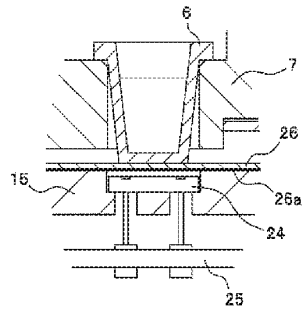


(1 7)

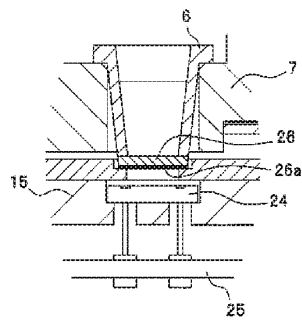
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【図5】

(a)

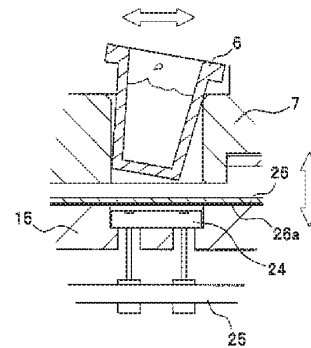


(b)

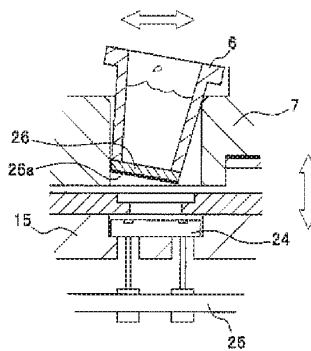


【図6】

(a)

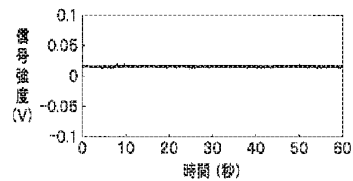


(b)

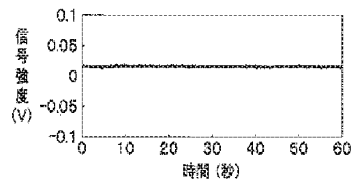


【図7】

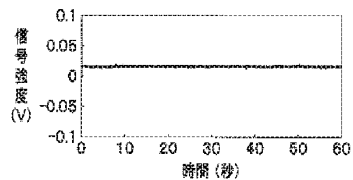
(a)



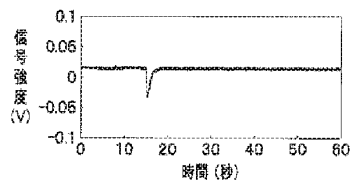
(b)



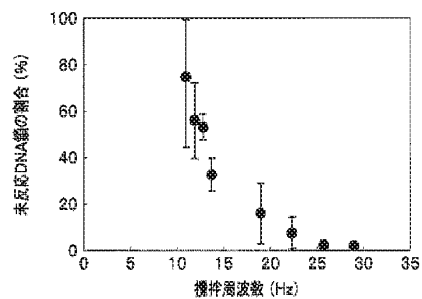
(c)



(d)



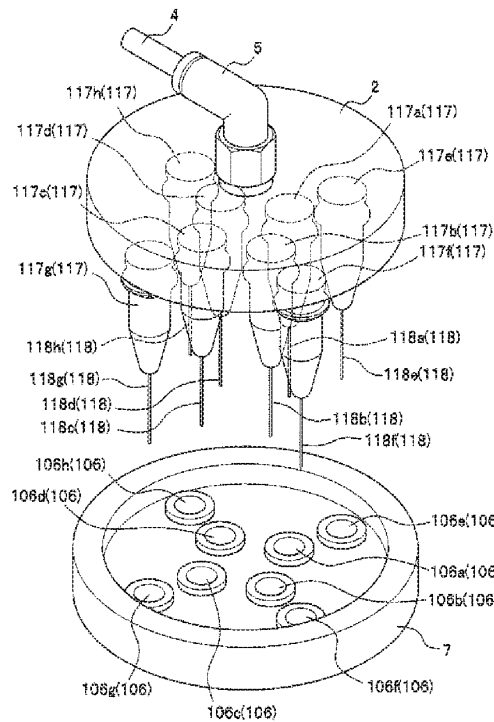
【図8】



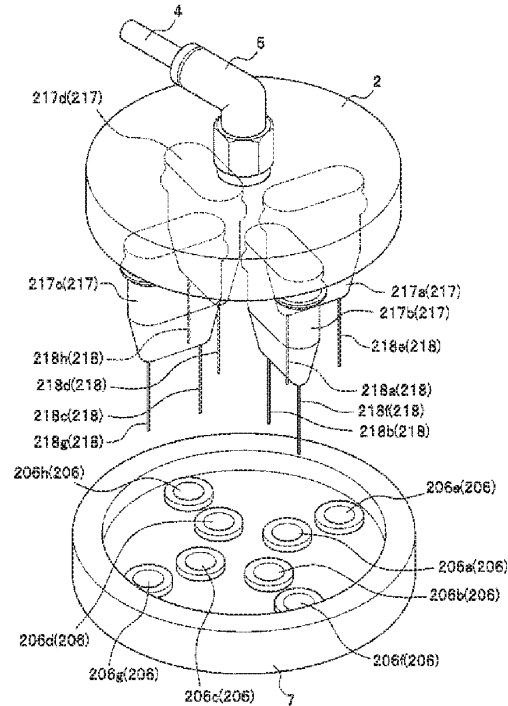
(1 8)

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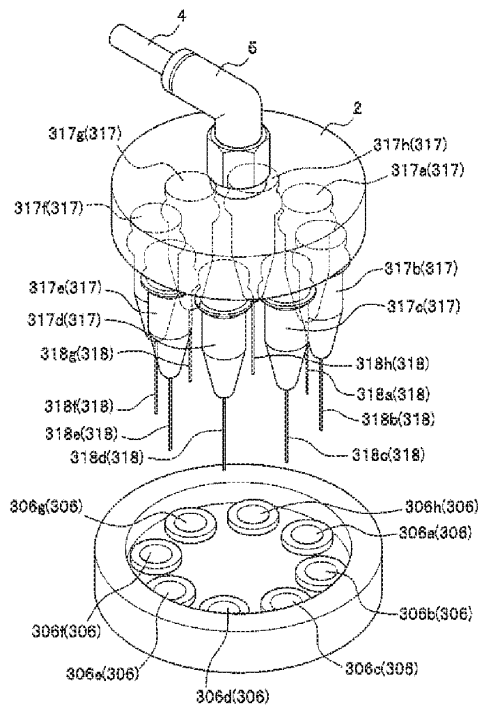
【図9】



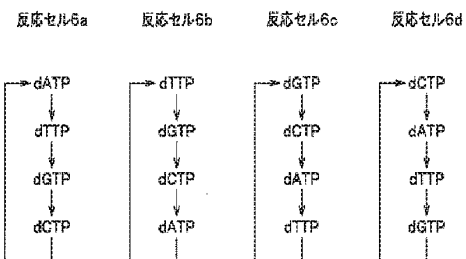
【図10】



【図11】



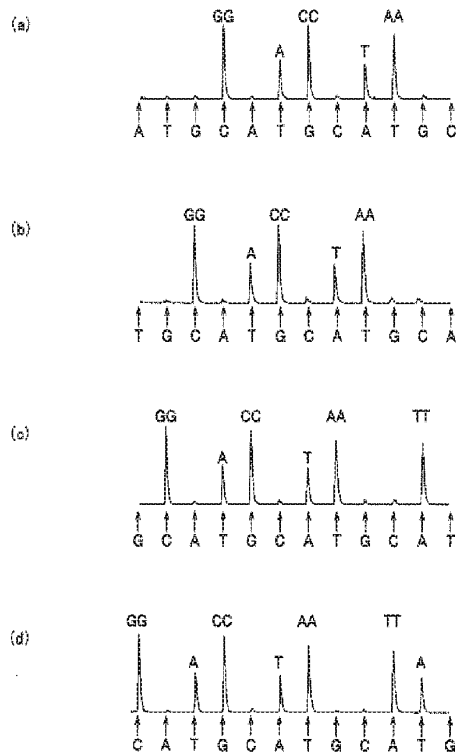
【図12】



(1 9)

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【図13】



【配列表】

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(2 0)

特開2006-177837 (P2006-177837A)

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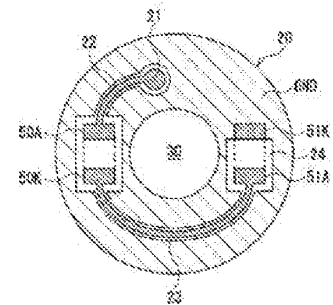
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(72)Inventor TAKAHASHI AKIHIRO

(54)ENDOSCOPE**(57)Abstract**

PROBLEM TO BE SOLVED: To obtain a high heat sink effect in an endoscope having a light emitting element provided at a distal end of an insertion unit.

SOLUTION: The endoscope comprises a printed circuit board 20 provided at the distal end of the insertion unit to mount two LEDs. A current is supplied through a shielded cable to the endoscope. The circuit board 20 has square lands 50A, 50K for mounting the first LED and square lands 51A, 51K for mounting the second LED. The land 50A in which an anode terminal of the first LED is mounted, is connected to a circular land 21 to which a core wire of the cable is connected, via a conductor pattern 22. The land 50K in which a cathode terminal of the first LED is mounted, is connected to the land 51A in which an anode terminal of the second LED is mounted, via a conductor pattern 23. A region except the conductor pattern 22 the lands 21 50A, 50K, the pattern 23, the lands 51A, 51K and an insulating region 24 for edging them is all formed as a conductor pattern GND for a ground.

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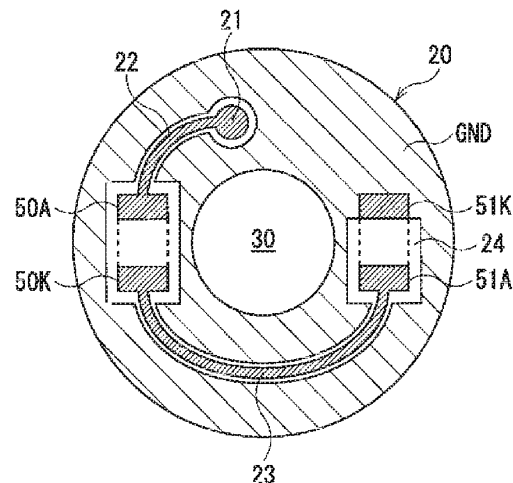
SS01

(54) 【発明の名称】 内視鏡

(57) 【要約】

【課題】 挿入部の先端に発光素子が設けられる内視鏡において高い放熱効果を得る。

【解決手段】 2つのLEDを実装するためのプリント配線板20を内視鏡挿入部の先端に設け、シールドケーブルを介して電流を供給する。プリント配線板20に第1のLEDを搭載するための角ランド50A、50Kと、第2のLEDを搭載するための角ランド51A、51Kを設ける。第1のLEDのアノード端子が取り付けられる角ランド50Aを導体パターン22を介してシールドケーブルの心線が接続される円形ランド21に連絡する。第1のLEDのカソード端子が取り付けられる角ランド50Kを導体パターン23を介して第2のLEDのアノード端子が取り付けられる角ランド51Aに連絡する。プリント配線板20の導体パターン21、22、50A、50K、23、51A、51Kとこれらを縁取る絶縁領域24を除く領域を全てグラウンド用導体パターンGNDとする。



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【特許請求の範囲】

【請求項1】 照明用光源として少なくとも1つの発光素子と、前記発光素子が実装され内視鏡の挿入部先端に配置されるプリント配線板とを備え、前記プリント配線板の表面のうち、グランド以外の信号用導体パターンが占める領域及び絶縁領域を除く領域がグランド用導体パターンとして成形されることを特徴とする内視鏡。

【請求項2】 前記発光素子が発光ダイオードであり、前記内視鏡が更に前記発光ダイオードの発光を制御するための電流を供給するドライブ回路と、前記ドライブ回路から前記プリント配線板に実装された前記発光ダイオードへ前記電流を供給するためのシールドケーブルとを備え、前記シールドケーブルのシールド部が前記グランド用導体パターンに接続されることを特徴とする請求項1に記載の内視鏡。

【請求項3】 前記発光ダイオードの少なくとも1つのカソード端子がグランド用導体パターンに接続されると共に、前記シールドケーブルが前記シールド部によりシールドされる1本の信号線を有し、前記電流の供給が前記1本の信号線と前記シールド部とを介して行われることを特徴とする請求項2に記載の内視鏡。

【請求項4】 前記シールドケーブルが前記シールド部によりシールドされる2本の信号線を有し、前記電流の供給が前記2本の信号線を介して行われることを特徴とする請求項2に記載の内視鏡。

【請求項5】 前記発光素子の少なくとも1つの端子がグランド用導体パターンに接続されることを特徴とする請求項1に記載の内視鏡。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、内視鏡の照明用光源の放熱構造に関する。

【0002】

【従来の技術】近年、発光ダイオード(LED)等の発光素子の性能が向上したこととともない、内視鏡の挿入部先端に光源であるLEDを設けることが提案されている。このような内視鏡では、ライトガイドを介することなく照明光を観察部位に供給することができるため、内視鏡挿入部の細径化が容易になるとともに、別途光源部を設ける必要がなくなるため、その構成も簡略・小型とすることができる。

【0003】

【発明が解決しようとする課題】上記構成を適用した従来の携帯内視鏡の一例を図7に示す。内視鏡本体100は、細長で可撓性を有する挿入部110、操作を行うための操作部120、及び内視鏡観察を行うための接眼部130から概ねなる。観察部位の映像は、挿入部110の先端部110Aに設けられた対物レンズ140を介し、超極細の光ファイバーの束からなるイメージガイド

(CFB)150により光学的に接眼部130まで伝送され、接眼部130に設けられた接眼レンズ160を通して観察される。また、先端部110Aには、例えば複数のLEDを備えた光源部170が設けられ、LEDの発光は、操作部120内に設けられたLEDドライブ回路180から信号線190を介して供給される電流により制御される。

【0004】ところで、LED等の発光素子の発光特性は、温度の上昇とともに劣化するという特性がある。また、内視鏡の先端部110Aは小型であるとともに気密性が高いため放熱効率が悪い。したがって、上述のように内視鏡先端部110AにLEDが設けられると、点灯時間の経過とともにLEDから発生する熱等によりLED自身及びその周辺の温度が上昇し、照明光の分光・配光特性が悪化するという問題がある。

【0005】本発明は、上記問題を解決するためになされたものであり、挿入部の先端に発光素子が設けられるとともに放熱効果の高い内視鏡を得ることを目的としている。

【0006】

【課題を解決するための手段】本発明の内視鏡は、照明用光源として少なくとも1つの発光素子と、発光素子が実装され内視鏡の挿入部先端に配置されるプリント配線板とを備え、プリント配線板の表面のうち、グランド以外の信号用導体パターンが占める領域を除く領域及び絶縁領域がグランド用導体パターンとして成形されることを特徴としている。

【0007】内視鏡は例えば、発光素子が発光ダイオードであり、更に発光ダイオードの発光を制御するための電流を供給するドライブ回路と、ドライブ回路からプリント配線板に実装された発光ダイオードへ電流を供給するためのシールドケーブルとを備え、シールドケーブルのシールド部はグランド用導体パターンに接続される。また、発光ダイオードの少なくとも1つのカソード端子がグランド用導体パターンに接続されると共に、シールドケーブルがシールド部によりシールドされる1本の信号線を有し、電流の供給が1本の信号線とシールド部とを介して行われる。他方、シールドケーブルは例えば、シールド部によりシールドされる2本の信号線を有し、電流の供給は2本の信号線を介して行われる。これによりグランド用導体パターンに逃れた熱はさらにシールドケーブルのシールド部や信号線を介して放熱され、放熱効果はより向上される。また、電力供給にシールドケーブルを用いることにより、外来または放射ノイズの影響を抑制することができる。また、例えば発光素子の少なくとも1つの端子はグランド用導体パターンに接続される。これにより、より効率よく発光素子で発生する熱をグランド用導体パターンに逃がすことができる。

【0008】

【発明の実施の形態】以下、本発明の実施の形態を、図

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面を参照して説明する。図1は、本発明を適用した第1の実施形態である携帯内視鏡の構成の概略を示す図である。

【0009】内視鏡本体10は、細長で可撓性を有する挿入部11、操作を行うための操作部12、及び内視鏡観察を行うための接眼部13から概ねなる。観察部位の映像は、挿入部11の先端部11Aに設けられた対物レンズ14を介し、超極細の光ファイバーの束からなるイメージガイド(CFB)15により光学的に接眼部13まで伝送され、接眼部13に設けられた接眼レンズ16を通して観察される。また、先端部11Aには、発光素子として例えば2つのLED50、51(図2参照)を備えた光源部17が設けられる。LED50、51の発光は、操作部12内に設けられたLEDドライブ回路18からシールドケーブル19を介して供給される電流により制御される。なお、内視鏡本体10内には、イメージガイド15の他に例えば、鉗子チャンネル、送気・送水チャンネル、吸引チャンネル等が設けられ、操作部12には各種の操作ボタン等が設けられているが、これらについては図示を省略する。

【0010】図2には、LED50、51とLEDドライブ回路18の電気的な接続状態が示されている。図2に示されるように、光源部17に設けられたLED50、51は直列にLEDドライブ回路18に接続される。なお、LEDドライブ回路18の駆動/非駆動を制御して各LEDの点灯/非点灯を制御するON/OFFスイッチは図示を省略する。また、図1のシールドケーブル19の心線19AはLED50のアノード端子に接続され、図1のシールド部19KはLED51のカソード端子に接続される。

【0011】図3は、LED50、51が実装されるプリント配線板の導体パターンを示す。プリント配線板20は、内視鏡の先端部11Aの形状に合わせて例えば略円板状に成形され、その中央にはイメージガイド15の先端に設けられる対物レンズ14を挿通するための円形開口30が設けられている。プリント配線板20上には、例えば面実装タイプ等のLED50、51のアノード端子、カソード端子を接続するための長方形の角ランド50A、50K、51A、51Kが設けられている。角ランド50A、50Kには、LED50のアノード端子、カソード端子がそれぞれ接続され、角ランド51A、51Kには、LED50のアノード端子、カソード端子がそれぞれ接続される。角ランド50Aと角ランド51K、角ランド50Kと角ランド51Aは、プリント配線板20を二等分する直線を対称軸として略線対称な位置に配置される。角ランド50Aは導体パターンの連結部22を介して、シールドケーブル19の心線19Aが接続される円形ランド21に接続され、角ランド50Kは導体パターンの連結部23を介して角ランド51Aと接続される。

【0012】プリント配線板20上において、円形ランド21、角ランド50A、50K、51A、51K、連結部22、23からなる信号用導体パターンが形成された領域以外の領域は、略全面グランド用導体パターンGNDとして導電性部材で覆われている。すなわち、角ランド51Kを除く円形ランド21、角ランド50A、50K、51A、連結部22、23からなる信号用導体パターンは、これらの周縁を縁取るように取り囲んだ絶縁領域24(図3中の白抜きの領域)を挟んでグランド用導体パターンGNDに取り囲まれている。また、角ランド51Kは、グランド用導体パターンGNDと一体的に形成されている。グランド用導体パターンGNDはシールドケーブル19のシールド部19Kに接続され接地される。

【0013】以上のように、第1の実施形態では、直列に接続されるLEDの最後のカソード端子を接続するためのランドをプリント配線板のグランド用導体パターンと一体的に形成するとともに、LEDの他の電極が取り付けられるランド部及びこれらを連結する信号用導体パターン等を取り囲むようにグランド用導体パターンを形成することにより、極めて広いグランド用導体パターンを得ることができる。導電性材料からなる信号用導体パターン及びグランド用導体パターンは通常熱伝導性も高いので、LED及びその周辺で発生する熱を、信号用導体パターンまたは空中を介して効率よくグランド用導体パターン全面に伝導することができる。また、グランド用導体パターンはシールドケーブル15のシールド部15Kに接続されているため、LEDからの熱を配線板、グランド用導体パターンを介して熱伝導性のシールド部に逃がすことができる。したがって、第1の実施形態によれば、高い放熱効果が得られる。また、LEDには、シールドケーブル15を介して電力が供給されるので、外来または放射ノイズの影響を抑制することも同時に可能である。

【0014】次に、図4～図6を参照して、本発明を適用した第2の実施形態である携帯内視鏡について説明する。なお、第1の実施形態と同様の機能を果たす構成部には同一の参照番号を使用した。

【0015】図4は、第2の実施形態である携帯内視鏡の構成を概略的に示す図である。第2の実施形態における携帯内視鏡の構成は、第1の実施形態における携帯内視鏡の構成と略同様であり、異なるのはLEDが取り付けられるプリント配線板の導体パターンの形状と、LEDドライブ回路からLEDに電力を供給するためのシールドケーブルの構造である。以下、第1の実施形態とそれらの形状及び構造が異なる部分についてのみ説明する。

【0016】内視鏡の先端部11Aには、光源部17'が設けられ、光源部17'はシールドケーブル40によりLEDドライブ回路18と接続されている。シールド

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ケーブル40内には、ツイストペアとして構成された2本の信号線40A、40Kが配設されており、電流はこれらの信号線を介して光源部17'に設けられたLED50、51に供給される。

【0017】図5には、LED50、51とLEDドライブ回路18の電気的な接続状態が示されている。図5に示されるように、光源部17'に設けられたLED50、51は直列にLEDドライブ回路18に接続される。なお、LEDドライブ回路18の駆動/非駆動を制御して各LEDの点灯/非点灯を制御するON/OFFスイッチは図示を省略する。図4のシールドケーブル40の信号線40AはLED50のアノード端子に接続され、信号線40KはLED51のカソード端子に接続される。

【0018】図6は、LED50、51が実装されるプリント配線板の導体パターンを示す。プリント配線板20'は、第1の実施形態と同様に内視鏡の先端部11Aの形状に合わせて例えば略円板状に成形され、その中央にはイメージガイド15の先端に設けられる対物レンズ14を挿通するための円形開口30が設けられている。プリント配線板20'上には、LED50、51のアノード端子、カソード端子を接続するための角ランド50A、50K、51A、51K'が設けられている。角ランド50A、50K、51A、51K'の配置は、第1の実施形態における角ランド51Kを51K'と読み替えば、第1の実施形態と同様である。

【0019】角ランド50Aは導体パターンの連結部22を介して、シールドケーブル40の信号線40Aが接続される円形ランド21に接続され、角ランド50Kは導体パターンの連結部23を介して角ランド51Aと接続される。また、LED51のカソード端子が接続される角ランド51K'は導体パターンの連結部26を介して、シールドケーブル40の信号線40Kが接続される円形ランド25に接続される。

【0020】プリント配線板20'上において、角ランド50A、50K、51A、51K'、円形ランド21、25、連結部22、23、26とからなる信号用導体パターンが形成された領域以外の領域は、グラウンド用導体パターンGND'として導電性部材で覆われている。すなわち、角ランド50A、50K、51A、51K'、円形ランド21、25、連結部22、23、26とからなる信号用導体パターンは、これらの周縁を取り囲んだ絶縁領域24'（図6中の白抜き領域）を挟んでグラウンド用導体パターンGND'に取り囲まれている。

る。グラウンド用導体パターンGND'は図4のシールドケーブル40のシールド部40Gに接続され接地される。

【0021】以上により、第2の実施形態においても第1の実施形態と同様の効果を得ることができる。

【0022】なお、本実施形態では、LEDの数は2つであったが、LEDの数はこれに限定されるものではなく、これよりも多くても少なくともよい。また、LEDの配置も本実施形態の配置に限定されるものではない。

【0023】本実施形態では、携帯内視鏡を例にとって説明したが、本発明の適用は携帯内視鏡に限定されるものでないことは勿論のことであり、通常のファイバースコープや、電子内視鏡装置における電子スコープに用いてもよい。

【0024】

【発明の効果】以上のように、本発明によれば、挿入部の先端に発光素子が設けられた内視鏡において、高い放熱効果を得ることができる。

【図面の簡単な説明】

【図1】本発明が適用される第1の実施形態の携帯内視鏡の概略図である。

【図2】第1の実施形態における内視鏡の先端部に設けられるLEDの電気的構成を概略示す図である。

【図3】第1の実施形態においてLEDが実装されるプリント配線板の導体パターンを示す図である。

【図4】本発明が適用される第2の実施形態の携帯内視鏡の概略図である。

【図5】第2の実施形態における内視鏡の先端部に設けられるLEDの電気的構成を概略示す図である。

【図6】第2の実施形態においてLEDが実装されるプリント配線板の導体パターンを示す図である。

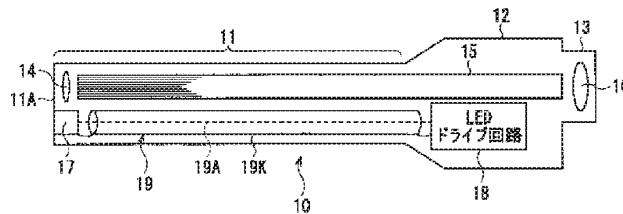
【図7】内視鏡の先端部にLEDを設けた従来の携帯内視鏡の一例を示す図である。

【符号の説明】

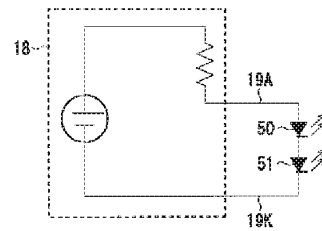
10 内視鏡
11 挿入部
11A 先端部
17 光源部
19、40 シールドケーブル
20、20' プリント配線板
21、25 円形ランド
50A、50K、51A、51K、51K' 角ランド
50、51 LED
GND、GND' グラウンド用導体パターン

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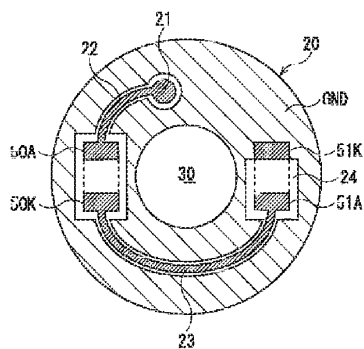
【図1】



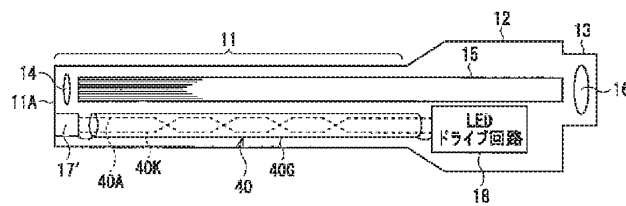
【図2】



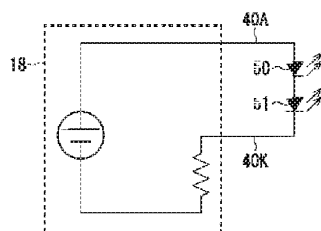
【図3】



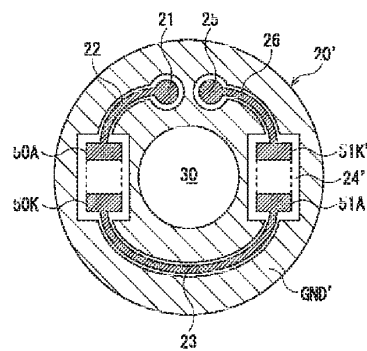
【図4】



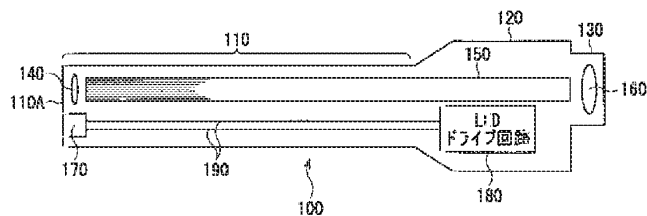
【図5】



【図6】



【図7】

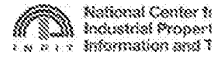


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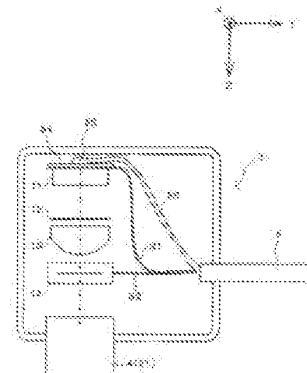
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(54)HEAD-MOUNTED DISPLAY

(57)Abstract

PROBLEM TO BE SOLVED: To avoid a decline in image brightness or deterioration in the quality of parts of an HMD (head-mounted display), by efficiently making the heat, generated by a light source 11, lead to the outside of a casing 3 and dissipate efficiently.

SOLUTION: An image display device of an HMD has a light source 11 that has an LED and a heat-absorbing member 34 inside a casing 3. The light source 11 is soldered to a land portion of the FPC 3. The heat-absorbing member 34 is placed on a side opposite to the surface where the light source 11 of the FPC 31 is mounted. The heat-absorbing member 34 is connected to a shielded cable 62 of a cable 6 by soldering 35. Since the land portion has a fixed area in the FPC 31 and the heat-absorbing member 34 has a fixed area with respect to the FPC 31, the heat generated by the light source 11 is dissipated efficiently from the surface of the land portion of the FPC 31, and is then, via an insulating layer of the FPC 31, absorbed efficiently via the surface of the heat-absorbing member 34, and is thereafter led out of the casing 3 and transferred to the outside via the shielded cable 62.

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(19) 日本国特許庁 (JP)

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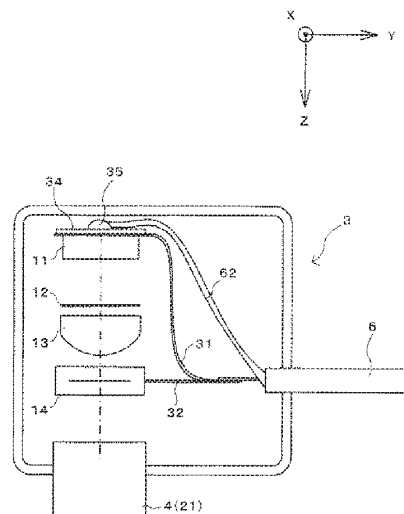
(54) 【発明の名称】 ヘッドマウントディスプレイ

(57) 【要約】

【課題】 HMDにおいて、光源11にて発生した熱を効率よく筐体3の外部に導いて放熱させることにより、映像輝度の低下や部品の劣化を回避する。

【解決手段】 HMDの映像表示装置は、LEDからなる光源11と、吸熱部材34とを筐体3内に有している。光源11は、FPC31のランド部分に半田付けにより実装されている。吸熱部材34は、FPC31における光源11の実装面とは反対側の面に配置されている。吸熱部材34は、ケーブル6のシールド線62と半田35により接続されている。上記のランド部分はFPC31において一定の面積を有し、吸熱部材34もFPC31に対して一定の面積を有するので、光源11にて発生した熱は、FPC31のランド部分の面から効率よく放出され、FPC31の絶縁層を介して吸熱部材34の面で効率よく吸収された後、シールド線62を介して筐体3の外部に伝達され、放熱される。

【選択図】 図1



(2)

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【特許請求の範囲】

【請求項1】

映像表示素子を内包し、かつ、接眼光学系の一部を保持する筐体を有する映像表示装置と、

上記接眼光学系を観察者の眼前で支持する支持手段とを有し、上記映像表示素子からの映像光を上記接眼光学系を介して観察者の瞳に導くヘッドマウントディスプレイであって、

上記映像表示装置は、

上記筐体内の基板上に実装され、上記映像表示素子を照明する、発光ダイオードからなる光源と、

上記基板における上記光源の実装面とは反対側の面に配置され、上記光源からの熱を吸収する吸熱部材と、

上記吸熱部材にて吸収した熱を上記筐体の外部に導く熱伝導部材とを有していることを特徴とするヘッドマウントディスプレイ。

【請求項2】

上記基板は、フレキシブル回路基板であることを特徴とする請求項1に記載のヘッドマウントディスプレイ。

【請求項3】

上記発光ダイオードは、上記フレキシブル回路基板上に半田付けにより実装されていることを特徴とする請求項2に記載のヘッドマウントディスプレイ。

【請求項4】

上記吸熱部材は、上記フレキシブル回路基板における上記ランド部分と対向する部分を全て覆うように配置されていることを特徴とする請求項3に記載のヘッドマウントディスプレイ。

【請求項5】

上記吸熱部材は、熱伝導率100W/mK以上の金属材料からなる金属板で構成されていることを特徴とする請求項1から4のいずれかに記載のヘッドマウントディスプレイ。

【請求項6】

上記熱伝導部材は、熱伝導率100W/mK以上の金属材料からなることを特徴とする請求項請求項1から5のいずれかに記載のヘッドマウントディスプレイ。

【請求項7】

上記映像表示装置は、

上記光源および上記映像表示素子へケーブルを介して少なくとも駆動電力および映像信号を供給するための回路基板を有しており、

上記熱伝導部材は、上記ケーブルのシールド線であることを特徴とする請求項1から6のいずれかに記載のヘッドマウントディスプレイ。

【請求項8】

上記支持手段の少なくとも一部は、熱伝導率100W/mK以上の金属材料からなる支持側金属部で構成されており、

上記熱伝導部材は、上記吸熱部材と上記支持側金属部とを連結していることを特徴とする請求項1から6のいずれかに記載のヘッドマウントディスプレイ。

【請求項9】

上記筐体の少なくとも一部は、熱伝導率100W/mK以上の金属材料からなる筐体側金属部で構成されており、

上記筐体側金属部は、外部に露出しており、

上記熱伝導部材は、上記吸熱部材と上記筐体側金属部とを連結していることを特徴とする請求項1から6のいずれかに記載のヘッドマウントディスプレイ。

【請求項10】

上記接眼光学系は、体積位相型で反射型のホログラム光学素子を有しており、

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上記ホログラム光学素子は、上記映像表示素子からの映像光を回折反射させて観察者の瞳に導くことを特徴とする請求項1から9のいずれかに記載のヘッドマウントディスプレイ。

【請求項11】

上記ホログラム光学素子は、上記映像表示素子からの映像光と外光とを同時に観察者の目に導くコンバイナであることを特徴とする請求項10に記載のヘッドマウントディスプレイ。

【請求項12】

上記ホログラム光学素子の回折効率ピークの半値波長幅は、5nm以上10nm以下であることを特徴とする請求項11に記載のヘッドマウントディスプレイ。

【請求項13】

上記光源は、発光強度がピークとなる波長の異なる複数の発光ダイオードで構成されていることを特徴とする請求項1から12のいずれかに記載のヘッドマウントディスプレイ。

【請求項14】

上記光源は、3原色に対応した光を発光する3つの発光部を偶数組有しており、

上記ホログラム光学素子への光軸の入射面に対して垂直な方向における各発光部の配列順序が、隣接する各組間で逆であることを特徴とする請求項13に記載のヘッドマウントディスプレイ。

【発明の詳細な説明】

【技術分野】

【0001】

本発明は、映像表示素子からの映像光を接眼光学系を介して観察者の瞳に導くヘッドマウントディスプレイ（以下、HMDとも称する）に関するものである。

【背景技術】

【0002】

観察者の頭部に装着され、映像表示素子にて生成された映像を接眼光学系を介して観察者の瞳に虚像投影する装置は、いわゆるHMDと呼ばれ、一般に知られている。このようなHMDは、上記の映像表示素子やその映像表示素子を照明する光源を筐体内部に有している。近年、HMDは小型、軽量なものが開発されるようになり、上記光源として小型で安価な発光ダイオード（以下、LEDとも称する）が一般的に用いられるようになってきている。

【0003】

ところで、HMDを長時間使用すると、LEDの発熱による筐体内部の温度上昇により、映像表示輝度の低下や部品の劣化（例えば部品の熱による変形）などの不具合が発生することがある。そのため、例えば特許文献1および2では、装置内部に冷却ファンを設け、装置内部の温度上昇を抑制する手法が採られている。しかし、頭部搭載型の装置に冷却ファンを設けると、装置が大型になって重くなるため、その装置を頭部に装着する観察者は、その装置の長時間の使用がしづらくなる。

【0004】

一方、例えば特許文献3では、LEDにて発生した熱を、冷却ファンを用いずに外部に逃がす手法が提案されている。より具体的には、プリント配線板上で、LEDと電氣的に接続される信号用導体パターンを、絶縁領域を介してグラウンド用導体パターンと並べて配置している。なお、上記の絶縁領域とは、導体パターンのない領域であり、信号用導体パターンの周縁を取り囲むように形成されている。また、上記のグラウンド用導体パターンは、LEDに電流を供給するためのケーブルのシールド部を介して接地されている。

【0005】

この構成により、LEDにて発生した熱は、信号用導体パターンから絶縁領域を介してグラウンド用導体パターンに伝達され、さらにケーブルのシールド部を介して放熱される。

【0006】

【特許文献1】特開平6-175066号公報

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【特許文献2】特開平9-34376号公報

【特許文献3】特開2003-24276号公報

【発明の開示】

【発明が解決しようとする課題】

【0007】

ところで、特許文献3においては、LEDからの熱は、信号用導体パターンのエッジから、絶縁領域を介して同一面内にあるグランド用導体パターンに伝達される。しかも、上記絶縁領域の材料となるプリント配線板の基材として一般的に使用される紙フェノールやガラスエポキシ材は、その熱伝導率が0.3W/mKと低い。

【0008】

このため、特許文献3の手法では、LEDにて発生した熱がグランド用導体パターンに伝達されにくく、その結果、LEDにて発生した熱を効率よく筐体外部に導いて放熱させることができないと考えられる。

【0009】

本発明は、上記の問題点を解決するためになされたものであって、その目的は、光源にて発生した熱を効率よく筐体外部に導くことができ、これによって、映像輝度の低下や部品の劣化を回避することができるヘッドマウントディスプレイを提供することにある。

【課題を解決するための手段】

【0010】

本発明のヘッドマウントディスプレイは、映像表示素子を内包し、かつ、接眼光学系の一部を保持する筐体を有する映像表示装置と、上記接眼光学系を観察者の眼前で支持する支持手段とを有し、上記映像表示素子からの映像光を上記接眼光学系を介して観察者の瞳に導くヘッドマウントディスプレイであって、上記映像表示装置は、上記筐体内の基板上に実装され、上記映像表示素子を照明する、発光ダイオードからなる光源と、上記基板における上記光源の実装面とは反対側の面に配置され、上記光源からの熱を吸収する吸熱部材と、上記吸熱部材にて吸収した熱を上記筐体の外部に導く熱伝導部材とを有していることを特徴としている。なお、上記基板は、フレキシブル回路基板（以下、FPCとも称する）であってもよく、上記発光ダイオードは、上記フレキシブル回路基板上に半田付けにより実装されていてもよい。

【0011】

上記の構成によれば、LEDからなる光源を点灯させて映像表示素子を照明すると、映像表示素子に表示された映像光が観察者の眼前に位置する接眼光学系を介して観察者の瞳に導かれる。これにより、観察者は映像を観察することが可能となる。

【0012】

ここで、上記の光源は、筐体内の基板上（例えばFPCのランド部分）に（例えば半田付けにより）実装されている。一方、基板における光源の実装面とは反対側の面には、吸熱部材が配置されている。これにより、光源にて発生した熱を、上記基板から効率よく放出させて吸熱部材の面で効率よく吸収することができる。特に、基板がFPCで構成される場合は、FPCのランド部分はFPCにおいて一定の面積を有し、吸熱部材もFPCに対して一定の面積を有するので、光源にて発生した熱を、上記ランド部分の面から効率よく放出することができるとともに、その放出された熱を、FPCを介して吸熱部材の面で効率よく吸収することができる。そして、吸熱部材にて吸収された熱を、熱伝導部材を介して筐体外部に導き、そこで放出することができる。つまり、上記構成によれば、光源にて発生した熱を効率よく筐体外部に導いて放出し、光源の発熱に起因して起こる映像輝度の低下や部品の劣化を回避することが可能となる。

【0013】

また、本発明において、上記吸熱部材は、上記フレキシブル回路基板における上記ランド部分と対向する部分を全て覆うように配置されていることが望ましい。この場合、FPC裏面（光源実装面とは反対側の面）に配置される吸熱部材は、FPC表面に実装される

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光源から発生した熱を、上記ランド部分を介して、FPCの厚さ分の最小距離で吸収することができ、光源からランド部分に伝達された熱を、吸熱部材が吸収しやすくなる。

【0014】

また、上記吸熱部材は、熱伝導率 $100\text{W}/\text{mK}$ 以上の金属材料からなる金属板で構成されていることが望ましい。この場合、吸熱部材での高い吸熱効率を実現することができる。また、吸熱部材がそのような金属板で構成されているので、吸熱部材の加工およびその吸熱部材のFPCへの貼り付けが容易となる。

【0015】

また、上記熱伝導部材は、熱伝導率 $100\text{W}/\text{mK}$ 以上の金属材料からなることが望ましい。この場合、吸熱部材にて吸収した熱が熱伝導部材に伝わりやすくなり、熱伝導部材を介して筐体外部で効率よく放熱させることができる。

【0016】

また、上記映像表示装置は、上記光源および上記映像表示素子へケーブルを介して少なくとも駆動電力および映像信号を供給するための回路基板を有しており、上記熱伝導部材は、上記ケーブルのシールド線であってもよい。

【0017】

この構成では、光源にて発生した熱は、FPCを介して吸熱部材にて吸収され、さらに熱伝導部材であるシールド線を介して筐体外部に導かれる。シールド線は、電磁波を遮蔽する目的で元ケーブルに設けられているものであるため、上記構成によれば、既存のシールド線を有効利用して、光源の放熱を図ることができる。また、筐体の内部から外部にかけてケーブルが設けられていれば、吸熱部材にて吸収した熱を、熱伝導部材（シールド線）を介して筐体外部に容易にかつ確実に導くことができる。

【0018】

また、上記支持手段の少なくとも一部は、熱伝導率 $100\text{W}/\text{mK}$ 以上の金属材料からなる支持側金属部で構成されており、上記熱伝導部材は、上記吸熱部材と上記支持側金属部とを連結していてもよい。この構成では、光源にて発生した熱は、FPCを介して吸熱部材にて吸収され、さらに熱伝導部材を介して支持側金属部に導かれる。これにより、上記支持側金属部での放熱を図ることができる。また、支持側金属部は、熱伝導率 $100\text{W}/\text{mK}$ 以上の金属材料からなるため、吸熱部材からの熱が支持側金属部に伝達されやすくなる。

【0019】

また、上記筐体の少なくとも一部は、熱伝導率 $100\text{W}/\text{mK}$ 以上の金属材料からなる筐体側金属部で構成されており、上記筐体側金属部は、外部に露出しており、上記熱伝導部材は、上記吸熱部材と上記筐体側金属部とを連結していてもよい。この構成では、光源にて発生した熱は、FPCを介して吸熱部材にて吸収され、さらに熱伝導部材を介して筐体側金属部に導かれる。筐体側金属部は外部に露出しているため、筐体側金属部に導かれた熱をそこで外部に放熱させることができる。また、筐体側金属部は、熱伝導率 $100\text{W}/\text{mK}$ 以上の金属材料からなるため、吸熱部材からの熱が筐体側金属部に伝達されやすくなる。

【0020】

また、上記接眼光学系は、体積位相型で反射型のホログラム光学素子を有しており、上記ホログラム光学素子は、上記映像表示素子からの映像光を回折反射させて観察者の瞳に導く構成であってもよい。体積位相型で反射型のホログラム光学素子は、回折効率ピークの半値波長幅が狭く、また、回折効率が高いので、このようなホログラム光学素子を用いることにより、色純度が高く、明るい映像を提供することができる。また、光源と瞳との共役関係が変更されないため、映像光の波長が変化せず、色再現性の高い映像を提供することができる。

【0021】

また、上記ホログラム光学素子は、上記映像表示素子からの映像光と外光とを同時に観察者の目に導くコンバイナであってもよい。この場合、観察者は、ホログラム光学素子を

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介して、映像表示素子から提供される映像と外界像とを同時に観察することができる。

【0022】

また、上記ホログラム光学素子の回折効率ピークの半値波長幅は、5 nm以上10 nm以下であることが望ましい。このように、ホログラム光学素子の回折効率ピークの半値波長幅が5 nm以上10 nm以下と狭ければ、観察者は色純度が高くて明るい映像を観察することができるとともに、外界像の光の透過率が高くなるので、観察者は明るい外界像を観察することができる。

【0023】

また、上記光源は、発光強度がピークとなる波長の異なる複数の発光ダイオードで構成されていてもよい。この構成では、複数の光源を用いて映像表示素子を照明するので、映像表示素子にてカラー映像を表示することが可能となり、そのカラー映像を観察者に提供することが可能となる。また、複数の光源を用いるので、色再現性が高く、明るい映像表示が可能となる。

【0024】

また、上記光源は、3原色に対応した光を発光する3つの発光部を偶数組有しており、上記ホログラム光学素子への光軸の入射面に対して垂直な方向における各発光部の配列順序が、隣接する各組間で逆であってもよい。この場合、各発光部からの出射光の各色の光強度（各組間で足し合わせたもの）の重心が一致する（例えば上記入射面上に位置する）ので、瞳の中心またはその近傍で色ムラの少ない映像を観察者に提供することができる。

【発明の効果】

【0025】

本発明によれば、光源にて発生した熱を、基板から効率よく放出させて吸熱部材の面で効率よく吸収することができる。そして、吸熱部材にて吸収された熱を、熱伝導部材を介して筐体外部に導き、そこで放出することができる。つまり、光源にて発生した熱を効率よく筐体外部に導いて放出することができる。その結果、光源の発熱に起因して起こる映像輝度の低下や部品の劣化を回避することができる。

【発明を実施するための最良の形態】

【0026】

本発明の実施の一形態について、図面に基づいて説明すれば、以下の通りである。

【0027】

(1. HMDの構成)

図2は、本実施形態に係るHMDの概略の構成を示す斜視図である。HMDは、映像表示装置1と、支持手段2とで構成されている。

【0028】

映像表示装置1は、少なくとも光源11および映像表示素子14（ともに図3参照）を内包する筐体3を有している。この筐体3は、接眼光学系4の一部を保持している。接眼光学系4は、全体として眼鏡の一方のレンズ（図2では右眼用レンズ）のような形状をなしている。上記の支持手段2は、眼鏡のフレームに相当するものであり、接眼光学系4を観察者の眼前で支持する。また、映像表示装置1は、筐体3を貫通して設けられるケーブル6を介して、光源11および映像表示素子14に少なくとも駆動電力および映像信号を供給するための回路基板5を有している。

【0029】

観察者がHMDを頭部に装着し、映像表示素子14に映像を表示すると、その映像光が接眼光学系4を介して観察者の瞳に導かれる。これにより、観察者は、映像表示装置1の映像を虚像として観察することができる。また、これと同時に、観察者は、接眼光学系4を介して、外界像をシースルーで観察することができる。以下、映像表示装置1の詳細について説明する。

【0030】

(2. 映像表示装置の構成)

図3は、映像表示装置1の概略の構成を示す断面図であり、図4は、映像表示装置1に

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おける光路を光学的に一方に展開して示す説明図である。映像表示装置1は、光源11と、一方向拡散板12と、集光レンズ13と、映像表示素子14と、上述した接眼光学系4とを有している。図3に示すように、光源11、一方向拡散板12、集光レンズ13および映像表示素子14は、筐体3内に収容されており、接眼光学系4の一部（後述する接眼プリズム21の一部）は、筐体3内に位置している。

【0031】

ここで、以下での説明の便宜上、方向を以下のように定義しておく。まず、映像表示素子14の表示領域の中心と、接眼光学系4によって形成される光学瞳Eの中心とを光学的に結ぶ軸を光軸とする。そして、光源11から光学瞳Eまでの光路を展開したときの光軸方向をZ方向とする。また、接眼光学系4の後述するホログラム光学素子23への光軸の入射面に垂直な方向をX方向とし、ZX平面に垂直な方向をY方向とする。なお、ホログラム光学素子23への光軸の入射面とは、ホログラム光学素子23における入射光の光軸と反射光の光軸とを含む平面、すなわち、YZ平面を指す。以下、上記入射面を単に入射面または光軸入射面と称する。

【0032】

光源11は、映像表示素子14を照明するものであり、本実施形態では、2組の光源群11P・11Qで構成されている。各光源群11P・11Qは、赤(R)、緑(G)、青(B)の3原色に対応する波長の光を発光する3つの発光部を有するRGB一体型のLEDで構成されている。

【0033】

ここで、図5は、光源11の各光源群11P・11Qの分光強度特性、すなわち、出射光の波長と光強度との関係を示す説明図である。各光源群11P・11Qは、例えば、光強度のピーク波長および光強度半値の波長幅で $462 \pm 12 \text{ nm}$ 、 $525 \pm 17 \text{ nm}$ 、 $635 \pm 11 \text{ nm}$ となる3つの波長帯域の光を発光する。なお、光強度のピーク波長とは、光強度がピークとなるときの波長のことであり、光強度半値の波長幅とは、光強度が光強度ピークの半値となるときの波長幅のことである。なお、図5の光強度は、B光の最大光強度を100としたときの相対値で示している。

【0034】

このように、光源11は、発光強度がピークとなる波長の異なる複数の発光部(LED)で構成されているので、映像表示素子14を照明したときに、映像表示素子14にてカラー映像を表示することが可能となり、そのカラー映像を観察者に提供することが可能となる。また、各LEDは、発光波長幅が狭いので、そのようなLEDを複数用いることにより、色再現性が高く、明るい映像表示が可能となる。

【0035】

一方向拡散板12は、光源11からの出射光を拡散させるものであるが、その拡散度は、方向によって異なっている。より詳細には、一方向拡散板12は、X方向には入射光を約 40° 拡散させ、Y方向には入射光を約 0.5° 拡散させる。また、一方向拡散板12は光源11側の面を光学的に平坦な面とし、集光レンズ13側の面を凹凸により拡散する凹凸面としている。それゆえ、光源11からの発散光が一方向拡散板12の平坦な面で屈折されてやや集光された状態で拡散されるので、集光状態が少し保存される。したがって、一方向拡散板12は凸レンズの機能を若干有しており、一方向拡散板12への入射光は光学瞳Eの形成に必要な方向に若干屈折する。

【0036】

集光レンズ13は、一方向拡散板12にて拡散された光をY方向に集光するシリンダレンズで構成されており、その拡散光が効率よく光学瞳Eを形成するように配置されている。本実施形態では、光学瞳Eは、X方向の大きさが6mmであり、Y方向の大きさが2mmとなっている。このように、光学瞳Eは、一方向(X方向)には人間の瞳(3mm程度)よりも大きい6mmの大きさなので、観察者は映像を観察しやすい。一方、光学瞳Eは、他の方向(Y方向)には人間の瞳よりも小さい2mmの大きさなので、光源11からの光は上記方向においては光学瞳Eに無駄なく集光する。これにより、観察者は、明るい映

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像を観察することができる。

【0037】

映像表示素子14は、光源11からの出射光を画像データに応じて変調して映像を表示するものであり、光が透過する領域となる各画素をマトリクス状に有する透過型の液晶表示素子で構成されている。映像表示素子14は、矩形的表示領域の長辺方向がX方向となり、短辺方向がY方向となるように配置されている。

【0038】

接眼光学系4は、接眼プリズム21（第1の透明基板）と、偏向プリズム22（第2の透明基板）と、ホログラム光学素子23とを有して構成されている。

【0039】

接眼プリズム21は、映像表示素子14からの映像光を内部で全反射させてホログラム光学素子23を介して観察者の瞳に導く一方、外光を透過させて観察者の瞳に導くものであり、偏向プリズム22とともに、例えばアクリル系樹脂で構成されている。この接眼プリズム21は、平行平板の下端部を下端に近くなるほど薄くして楔状にし、その上端部を上端に近くなるほど厚くした形状で構成されている。また、接眼プリズム21は、その下端部に配置されるホログラム光学素子23を挟むように、偏向プリズム22と接着剤で接合されている。

【0040】

偏向プリズム22は、平面視で略U字型の平行平板で構成されており（図2参照）、接眼プリズム21の下端部および両側面部（左右の各端面）と貼り合わされたときに、接眼プリズム21と一体となって略平行平板となるものである。この偏向プリズム22を接眼プリズム21に接合することにより、観察者が接眼光学系4を介して観察する外界像に歪みが生じるのを防止することができる。

【0041】

つまり、例えば、接眼プリズム21に偏向プリズム22を接合させない場合、外光は接眼プリズム21の楔状の下端部を透過するときに屈折するので、接眼プリズム21を介して観察される外界像に歪みが生じる。しかし、接眼プリズム21に偏向プリズム22を接合させて一体的な略平行平板を形成することで、外光が接眼プリズム21の楔状の下端部を透過するときの屈折を偏向プリズム22でキャンセルすることができる。その結果、シースルーで観察される外界像に歪みが生じるのを防止することができる。

【0042】

なお、接眼プリズム21および偏向プリズム22の各面（光入射面、光出射面）は、平面であってもよいし、球面であってもよい。接眼プリズム21および偏向プリズム22の各面を曲面とすれば、接眼光学系4に矯正眼鏡レンズとしての機能を持たせることもできる。

【0043】

ホログラム光学素子23は、映像表示素子14から出射される映像光（3原色に対応した波長の光）を回折反射し、映像表示素子14にて表示される映像を拡大して観察者の瞳に虚像として導く体積位相型の反射型ホログラムであり、軸非対称な正の光学パワーを有している。つまり、ホログラム光学素子23は、正のパワーを持つ非球面凹面ミラーと同様の機能を持っている。これにより、装置を構成する各光学部材の配置の自由度を高めて装置を容易に小型化するとともに、良好に収差補正された映像を観察者に提供することができる。また、ホログラム光学素子23は、映像表示素子14からの映像光と外光とを同時に観察者の瞳に導くコンバイナとして機能しており、観察者は、ホログラム光学素子23を介して、映像表示素子14から提供される映像と外界像とを同時に観察することができる。

【0044】

また、図6は、ホログラム光学素子23における回折効率の波長依存性を示す説明図である。同図に示すように、ホログラム光学素子23は、例えば、回折効率のピーク波長および回折効率半値の波長幅で465±5nm（B光）、521±5nm（G光）、634

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±5 nm (B光)の3つの波長域の光を回折(反射)させるように作製されている。ここで、回折効率のピーク波長とは、回折効率がピークとなるときの波長のことであり、回折効率半値の波長幅とは、回折効率が回折効率ピークの半値となるときの波長幅のことである。なお、図6の回折効率は、B光の最大回折効率を100としたときの相対値で示している。

【0045】

同図に示すように、体積位相型で反射型のホログラム光学素子23は、回折効率半値の波長幅が狭く、また、回折効率が高いので、このようなホログラム光学素子23を用いることにより、色純度が高く、明るい映像を提供することができるとともに、外光の透過率が高くなるので、観察者は明るい外界像を観察することができる。また、光源11と光学瞳Eとの共役関係が変更されないので、映像光の波長が変化せず、色再現性の高い映像を提供することができる。

【0046】

また、ホログラム光学素子23の回折効率ピークの半値波長幅が5 nm未満であると、回折波長幅が狭くなりすぎて、回折される光の光量が低下し、観察映像が暗くなることが懸念される。したがって、上記半値波長幅は、映像の明るさと色純度とのバランスを考慮して、5 nm以上10 nm以下に設定されていることが望ましい。つまり、上記半値波長幅が上記範囲に設定されていれば、映像の明るさと色純度とを両方満足させることができる。

【0047】

(3. 映像表示装置の動作について)

次に、上記構成の映像表示装置1の動作について説明する。光源11から出射された光は、一方向拡散板12にて拡散され、集光レンズ13にて集光されて映像表示素子14に入射する。映像表示素子14に入射した光は、画像データに基づいて各画素ごとに変調され、映像光として出射される。つまり、映像表示素子14には、カラー映像が表示される。

【0048】

映像表示素子14からの映像光は、接眼光学系4の接眼プリズム21の内部にその上端面から入射し、対向する2つの面で複数回全反射されて、ホログラム光学素子23に入射する。ホログラム光学素子23に入射した光は、そこで反射されて光学瞳Eに達する。光学瞳Eの位置では、観察者は、映像表示素子14に表示された映像の拡大虚像を観察することができる。

【0049】

一方、接眼プリズム21および偏向プリズム22は、外光をほとんど全て透過させるので、観察者は外界像を観察することができる。したがって、映像表示素子14に表示された映像の虚像は、外界像の一部に重なって観察されることになる。

【0050】

以上のように、映像表示装置1では、映像表示素子14から出射される映像光を、接眼プリズム21内での全反射によってホログラム光学素子23に導く構成としているので、通常の眼鏡レンズと同様に、接眼プリズム21および偏向プリズム22の厚さを3 mm程度にすることができ、映像表示装置1を小型化、軽量化することができる。また、映像表示素子14からの映像光を内部で全反射させる接眼プリズム21を用いることにより、高い外光の透過率を確保して、明るい外界像を観察者に提供することができる。

【0051】

(4. 筐体内の詳細な構成について)

次に、筐体3内の詳細な構成について説明する。図1は、本実施形態の映像表示装置1の筐体3内の構成を模式的に示す説明図である。また、図7は、上述したケーブル6の断面図である。

【0052】

光源11は、FPC31を介してケーブル6の信号線61と電気的に接続されており、

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映像表示素子14は、FPC32を介して他の信号線61と電気的に接続されている。ここで、ケーブル6は、複数の信号線61をシールド線62で1つに束ね、その外側を絶縁体からなるカバー63で覆うことによって形成されている。このような構成により、ケーブル6の複数の信号線61を介して、光源11および映像表示素子14に回路基板5(図2参照)からの駆動電力や映像信号を供給することが可能となっている。

【0053】

なお、信号線61の1本1本は、絶縁テープで巻かれて互いに絶縁されているものとする。また、シールド線62は、電磁波を遮蔽するものであるが、本実施形態では、熱伝導率100W/mK以上の金属材料からなっている。このような金属材料としては、例えば、銀(約420W/mK)、銅(約400W/mK)、アルミニウム(約250W/mK)、黄銅(約120W/mK)などがある。

【0054】

また、図8は、光源11とFPC31との接続部を模式的に示す断面図である。同図に示すように、FPC31は、圧延銅箔からなるランド部分31aを例えばポリイミドからなる絶縁層31b上に形成してなっている。ちなみに、ランド部分31aの厚さは例えば12.5mmであり、絶縁層31bの厚さは例えば12.5μmである。ランド部分31aは、熱伝導率100W/mK以上の金属材料であればどのような材料で構成されていてもよい。上記の光源11は、FPC31のランド部分31aに半田33を介して接着(半田付け)され、実装されている。

【0055】

一方、FPC31の裏面、すなわち、FPC31における光源11の実装面とは反対側の面には、吸熱部材34が接着、配置されている。吸熱部材34は、光源11からの熱を吸収するものであり、FPC31(絶縁層31b)におけるランド部分31aと対向する部分を全て覆うように配置されている。つまり、吸熱部材34は、FPC31のランド部分31aと対向してランド部分31a全体をカバーするように設けられている。また、吸熱部材34は、熱伝導率100W/mK以上の金属材料からなる金属板で構成されており、図1に示すように、ケーブル6のシールド線62と半田35により接着(半田付け)されている。

【0056】

このような構成により、光源11にて発生した熱は、半田33を介してランド部分31aに伝達される。そして、その熱は、ランド部分31aから絶縁層31bを介して吸熱部材34に伝達され、さらに、半田35およびシールド線62を介して筐体3の外部に伝達され、放熱される。

【0057】

このとき、ランド部分31aはFPC31の絶縁層31bに対して一定の面積を有し、吸熱部材34もFPC31に対して一定の面積を有するので、光源11にて発生した熱は、ランド部分31aの面から効率よく放出され、その放出された熱は、FPC31の絶縁層31bを介して吸熱部材34の面で効率よく吸収される。したがって、本実施形態の構成によれば、光源11にて発生した熱を効率よく筐体3の外部に導いて放出し、光源11の発熱に起因して起こる映像輝度の低下や部品の劣化を回避することが可能となる。なお、FPC31の絶縁層31bの厚さは例えば12.5μmと薄いので、ランド部分31aから吸熱部材34への熱の伝達において、絶縁層31bが大きな障害となることはない。

【0058】

また、吸熱部材34は、FPC31における複数のランド部分31aと対向する部分を全て覆うように配置されているので、光源11から発生した熱を、複数のランド部分31aを介して、FPC31の厚さ分の最小距離で効率よく吸収することができる。その結果、光源11から各ランド部分31aに伝達された熱を効率よく吸熱部材に伝達させ、吸収させることができる。

【0059】

さらに、本実施形態のように、光源11を複数の光源群11P・11Qで構成する場合

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でも、各光源群11P・11Qの各LEDのそれぞれで発生する熱を、各LEDと対応するランド部分31aを介して吸熱部材34に最小距離で伝達させることができる。したがって、各LEDの放熱が均等に進み、光源群11P・11Qの間でLEDの発光性能にばらつきが生じるのを回避することができる。

【0060】

また、吸熱部材34は、熱伝導率100W/mK以上の金属材料からなる金属板で構成されているので、吸熱部材34での高い吸熱効率を実現することができる。また、吸熱部材34が金属板で構成されるので、吸熱部材34の加工およびFPC31への貼り付けも容易となる。

【0061】

また、本実施形態では、吸熱部材34にて吸収した熱を筐体3の外部に導く熱伝導部材として、ケーブル6のシールド線62を用いている。これにより、ケーブル6にある既存のシールド線62を有効利用して光源11の放熱を図ることができる。また、シールド線62の利用により、吸熱部材34にて吸収した熱を、筐体3の内部から外部に容易にかつ確実に導くことができる。

【0062】

また、熱伝導部材としてのシールド線62が、熱伝導率100W/mK以上の金属材料からなっているため、吸熱部材34にて吸収した熱をシールド線62を介して筐体3の外部に効率よく導くことが容易となる。

【0063】

ところで、図9は、HMDの他の構成例を示す斜視図であり、図10は、そのHMDの筐体3内の詳細な構成を示す説明図である。このHMDでは、支持手段2が支持側金属部2aを有している。支持側金属部2aは、熱伝導率100W/mK以上の金属材料からなり、支持手段2の少なくとも一部を構成している。つまり、支持手段2の全体が支持側金属部2aで構成されていてもよい。一方、吸熱部材34（図10参照）には、熱伝導部材41が半田35により接続され、この熱伝導部材41が筐体3を貫通して支持手段2の支持側金属部2aと連結されている。熱伝導部材41は、熱伝導率100W/mK以上の金属材料で構成されている。

【0064】

この構成では、光源11にて発生した熱は、図8で示した半田33およびFPC31（ランド部分31a、絶縁層31b）を介して吸熱部材34にて吸収され、さらに半田35および熱伝導部材41を介して筐体3の外部の支持側金属部2aに導かれ、そこで放熱される。したがって、このような構成であっても、光源11の放熱を、筐体3の外部で図ることができる。

【0065】

特に、熱伝導部材41は、熱伝導率100W/mK以上の金属材料からなるので、吸熱部材34にて吸収した熱が熱伝導部材41に伝わりやすくなる。また、支持側金属部2aも熱伝導率100W/mK以上の金属材料からなるので、熱伝導部材41からの熱が支持側金属部2aに伝わりやすくなる。したがって、光源11にて発生した熱を、熱伝導部材41を介して支持側金属部2aに確実に伝達させることができ、そこで確実に放熱させることができる。

【0066】

また、図11は、HMDの筐体3内の他の構成を示す説明図である。この構成では、筐体3は、外部に露出した筐体側金属部3aを有している。筐体側金属部3aは、熱伝導率100W/mK以上の金属材料からなり、筐体3の少なくとも一部を構成している。つまり、筐体3の全体が筐体側金属部3aで構成されていてもよい。一方、吸熱部材34は、熱伝導部材42を介して筐体側金属部3aと連結されている。熱伝導部材42は、熱伝導率100W/mK以上の金属材料で構成されている。

【0067】

この構成では、光源11にて発生した熱は、FPC31（ランド部分31a、絶縁層3

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1 b)を介して吸熱部材34にて吸収され、さらに熱伝導部材42を介して筐体側金属部3aに導かれる。筐体側金属部3aは外部に露出しているため、上記構成によれば、筐体側金属部3aに導かれた熱を、そこで外部に放熱させることができる。

【0068】

特に、熱伝導部材42は、熱伝導率100W/mK以上の金属材料からなるので、吸熱部材34にて吸収した熱が熱伝導部材42に伝わりやすくなる。また、筐体側金属部3aも熱伝導率100W/mK以上の金属材料からなるので、熱伝導部材42からの熱が筐体側金属部3aに伝わりやすくなる。したがって、光源11にて発生した熱を、熱伝導部材42を介して筐体側金属部3aに確実に伝達させることができ、そこで確実に放熱させることができる。

【0069】

なお、ランド部分31aと、吸熱部材34と各熱伝導部材（シールド線62、熱伝導部材41・42）とは、同じ材料で構成されていてもよいし、異種材料で構成されてもよい。また、吸熱部材34と熱伝導部材41（または熱伝導部材42）とを必要に応じて一体形成することも可能である。

【0070】

また、熱を効果的に発散するためには、本実施形態のように光源11（LED）を半田付けによりFPC31のランド部分31aに搭載することが望ましいが、LEDの搭載方法はこれに限定されず、例えば接着剤（導電性を有するものであってもよい）によって接着するなど、他の方法であっても構わない。

【0071】

なお、本実施形態では、LEDが実装される基板としてFPC31を用いているが、LEDの配置形態によっては、上記基板は必ずしもフレキシブルな基板である必要はない。ただし、その基板の絶縁層は、本実施形態で説明したように十分に薄いことが望ましい。

【0072】

（5. 光源の各発光部の配列について）

次に、光源11の各発光部の配列について説明する。図12は、本実施形態における光源11を映像表示素子14側から見たときの平面図を示している。光源11の光源群11Pは、RGBの各色光を出射する3つの発光部11R₁・11G₁・11B₁を有するRGB一体型のLEDで構成されている。また、光源群11Qも同様に、RGBの各色光を出射する3つの発光部11R₂・11G₂・11B₂を有するRGB一体型のLEDで構成されている。

【0073】

各光源群11P・11Qの各発光部は、ホログラム光学素子23への光軸の入射面（YZ平面）に対して垂直な方向に並んで配置されているが、さらに、上記入射面に対して各色ごとに面対称となるように配置されている。より詳細には、発光部11R₁・11R₂が上記入射面に近い位置で面対称となるように配置され、そのX方向外側に発光部11G₁・11G₂が上記入射面に対して面対称となるように配置され、さらにそのX方向外側に発光部11B₁・11B₂が上記入射面に対して面対称となるように配置されている。つまり、各光源群11P・11Qでは、上記入射面側からX方向外側に向かうにつれて出射光の波長が短くなるような順序で、各発光部が配置されている。

【0074】

このように、各発光部を各色ごとに上記入射面に対して面対称に配置することにより、同じ色についての2つの発光部（例えば11R₁と11R₂）からの出射光の光強度を足し合わせたトータルの光強度の重心を、RGBの各色ともに対称面内（上記入射面内）に位置させることができる。つまり、RGBの各色ともにその強度分布を、対称面を中心にしてX方向に対称にすることができる。これにより、光学軸Eの中心において色ムラの少ない映像を観察者に提供することができる。

【0075】

なお、各発光部の面対称の中心となる面は、上記入射面に平行な面であってもよい。つ

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まり、各発光部の面対称の中心となる面は、上記入射面からX方向に多少ずれた面であっても構わない。この場合は、光学瞳Eの中心付近において色ムラの少ない映像を観察者に提供することができる。

【0076】

ところで、光源11が光源群2個で構成され、各発光部が各色ごとに面対称に配置される場合には、上記入射面に垂直な方向における各発光部の配列順序は、隣接する各組間で逆になる。一方、光源11を構成する光源群の個数が4個以上の偶数個であっても、つまり、光源11がRGBの各発光部を4組以上の偶数組設けて構成される場合でも、上記入射面に対して垂直な方向における各発光部の配列順序を隣接する各組間で逆にすれば、各発光部からの出射光の光強度を足し合わせたトータルの光強度の重心を、RGBの各色ともに上記入射面に平行な同一面（上記入射面を含む）内に位置させることができ、光学瞳Eの中心またはその近傍において色ムラの少ない映像を観察者に提供することができる。

【0077】

したがって、以上のことをまとめると、結局、光源11は、RGBの3つの発光部を2組以上の偶数組有しており、上記入射面に対して垂直な方向における各発光部の配列順序が隣接する各組間で逆であれば、光学瞳Eの中心またはその近傍において色ムラの少ない映像を観察者に提供できると言える。

【0078】

なお、本実施形態では、RGBの各発光部を2組設け、各組を個々のパッケージにした光源群11P・11Qで光源11を構成した例について説明したが、各組は1つのパッケージになっていてもよい。光源11の各光源群が1パッケージになっている場合には、光源11に熱が蓄積されやすく、光源11の温度が高くなりやすいが、この場合でも、本発明の放熱に関する構成を採用することにより、光源11にて発生した熱を効率よく筐体3またはその外部に伝達してそこで放熱させることができる。

【0079】

なお、例えば、吸熱部材34をシールド線62に接続するとともに、熱伝導部材41や熱伝導部材42とも接続するなど、本実施形態で説明した光源11の放熱に関する構成を組み合わせることで映像表示装置1についてはHMDを実現することも勿論可能である。

【図面の簡単な説明】

【0080】

【図1】本発明の実施の一形態に係るHMDにおける映像表示装置の筐体内の構成を模式的に示す説明図である。

【図2】上記HMDの概略の構成を示す斜視図である。

【図3】上記映像表示装置の概略の構成を示す断面図である。

【図4】上記映像表示装置における光路を光学的に一方方向に展開して示す説明図である。

【図5】上記映像表示装置の光源を構成する各光源群の分光強度特性を示す説明図である。

。【図6】上記映像表示装置のホログラム光学素子における回折効率の波長依存性を示す説明図である。

【図7】上記映像表示装置が有するケーブルの断面図である。

【図8】上記映像表示装置の光源とFPCとの接続部を模式的に示す断面図である。

【図9】上記HMDの他の構成例を示す斜視図である。

【図10】上記HMDの筐体内の詳細な構成を示す説明図である。

【図11】上記HMDの筐体内の他の構成を示す説明図である。

【図12】上記光源の映像表示素子側から見たときの平面図である。

【符号の説明】

【0081】

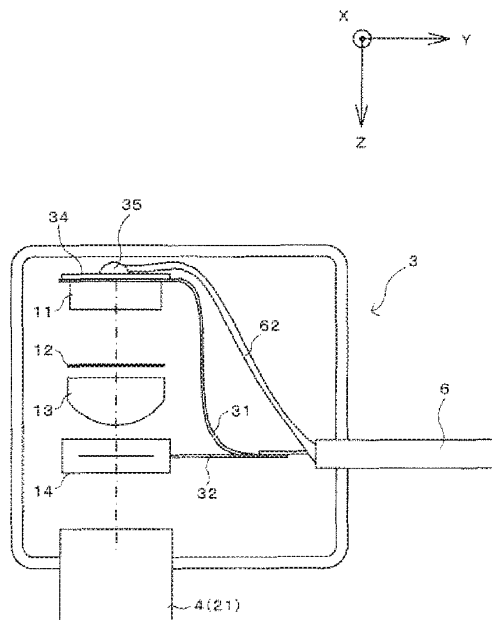
- 1 映像表示装置
- 2 支持手段
- 2a 支持側金属部

(1 4)

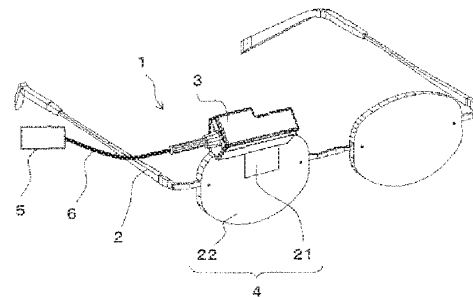
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- 3 筐体
- 3 a 筐体側金属部
- 4 接眼光学系
- 5 回路基板
- 6 ケーブル
- 11 光源
- 11 R₁、11 G₁、11 B₁ 発光部（光源、発光ダイオード）
- 11 R₂、11 G₂、11 B₂ 発光部（光源、発光ダイオード）
- 14 映像表示素子
- 23 ホログラム光学素子
- 31 FPC（フレキシブル回路基板）
- 31 a ランド部分
- 34 吸熱部材
- 41 熱伝導部材
- 42 熱伝導部材
- 61 信号線
- 62 シールド線（熱伝導部材）

【図1】



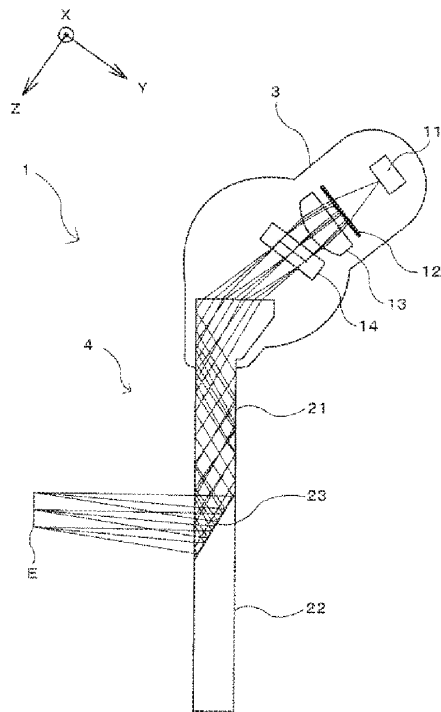
【図2】



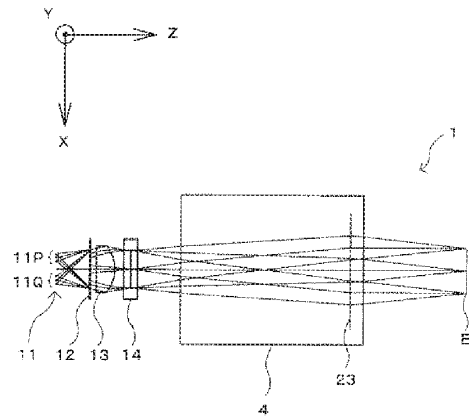
(1 5)

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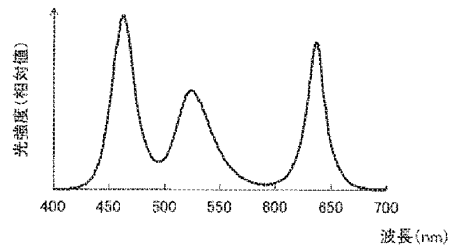
【図3】



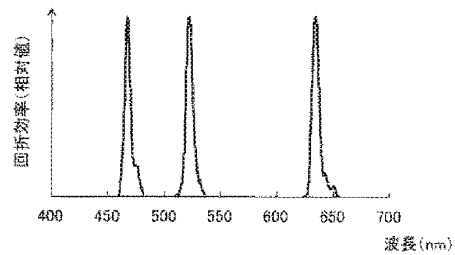
【図4】



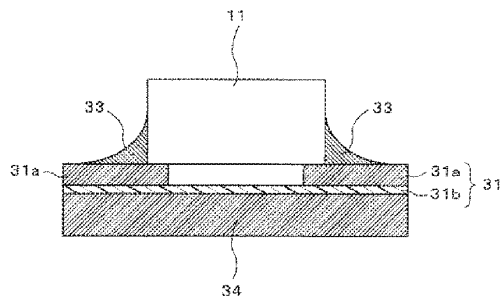
【図5】



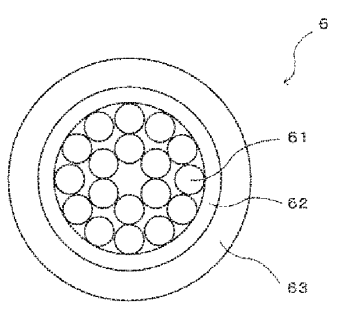
【図6】



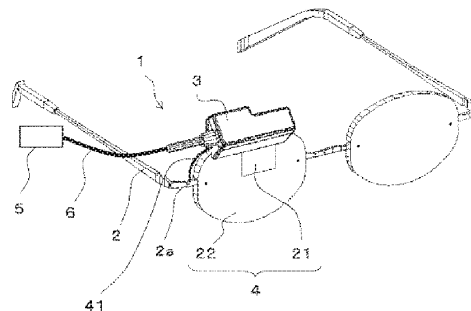
【図8】



【図7】



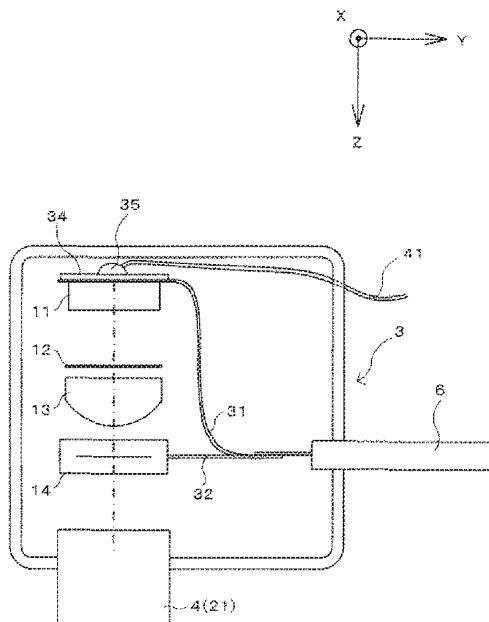
【図9】



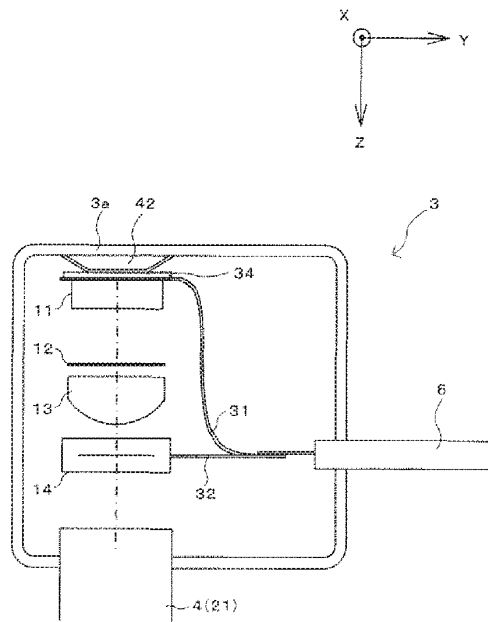
(1 6)

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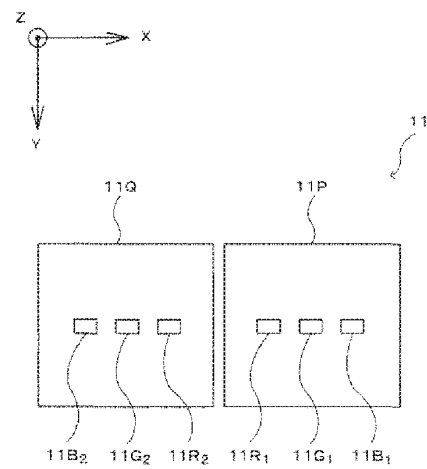
【図10】



【図11】



【図12】



CX-1622

(17)

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Espacenet

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COMPACT DEVICE FOR MEASURING TISSUE ANALYTES

Inventor(s):

Applicant(s):

Classification: - international: A61B5/00; A61B5/145; A61B5/1455;
(IPC1-7): A61B5/145
- cooperative: A61B5/0002; A61B5/14546; A61B5/14552;
A61B5/6826; A61B5/6838; A61B2560/0462;
A61B5/14532

Application number: JP20010519814 20000831

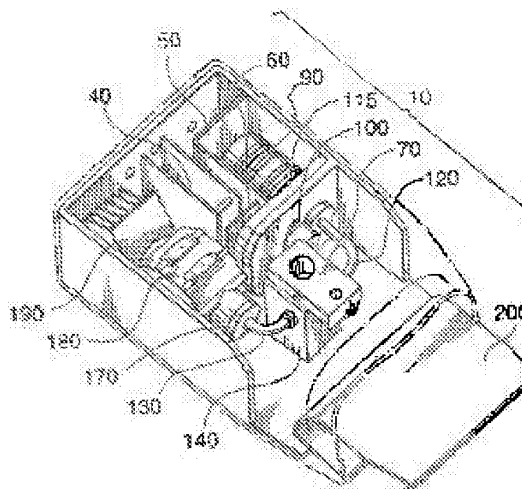
Priority number (s): US19990151538P 19990831 ; WO2000CA01004 20000831

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Abstract not available for JP2003508104 (A)

Abstract of corresponding document: WO0115595 (A1)

A compact device (10) for non-invasively monitoring concentration levels of blood constituents, including glucose, cholesterol, alcohol, blood gases and various ions. The device includes a finger receptor (140) having a channel for receiving a finger of a user. The channel has a light entrance and a light exit so that light can be passed from a light source (91) through a finger located in the channel in a direction generally normal to the finger. Certain heat generating components, including a stable power supply for the device, are external to the



device housing so as to reduce heat generation and thereby increase stability of the device. The device includes a communications interface for interacting with a computer. The device can be used for clinical use or for home use and the memory of the computer can be used to assist with record keeping and with dosage calculations.

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 (81) 指定国 EP(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), CA, JP, US

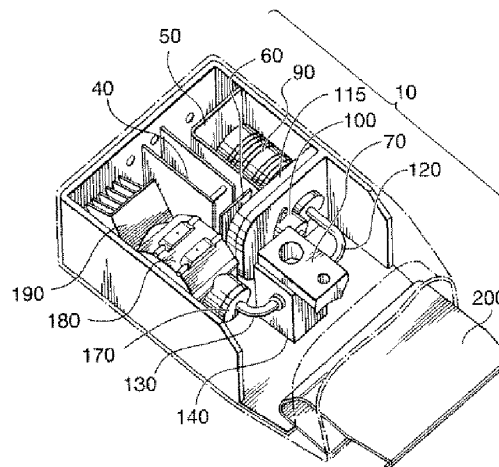
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最終頁に続く

(54) 【発明の名称】 組織成分測定のための小型装置

(57) 【要約】

小型装置(10)は、グルコース、コレステロール、アルコール、血液ガス及び種々のイオンを含む、血液成分の濃度レベルを非破壊的にモニタする。この装置は、ユーザの指を収容するための溝部を有する指収容部を備えている。溝部は光入口及び光出口を備え、光源(91)からの光が、溝部に置かれた指を、指にほぼ垂直な方向に通過できるようになっている。熱の発生を低減するため、装置用の安定電源を含む一部の熱発生構成要素は装置ハウジングの外部にあるので装置の安定性が高くなる。装置は、コンピュータと対話するための通信インタフェースを備えている。装置は、診療室又は自宅での使用に利用することができ、コンピュータのメモリは記録の保持及び投薬量計算を補助するのに用いることができる。



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【特許請求の範囲】

【請求項 1】 人間又は動物等の生体対象物の血液及び組織成分の濃度レベルを非破壊的に測定するための測定装置であって、

(a) 近赤外線帯域における光の広域スペクトル及び隣接可視光を発する多色光源と、

(b) 前記生体対象物の一部を収容するよう成形された収容部と、

(c) 前記光が前記対象物の一部分に導かれた後に、前記広域スペクトルにわたる連続波長を集める受光部と、

(d) 前記集めた光を、該集めた光の成分波長の分光スペクトルに分光するように、前記受光部に接続される分光手段と、

(e) 前記分光スペクトルからの吸光度測定値を取得して測定信号を生成するように、前記分光手段へ接続される光検出器と、

(f) 前記測定信号を外部コンピュータへ伝送するように、前記コンピュータに接続可能な通信インタフェースと、

(g) 外部の安定化電源に接続可能な電力インタフェースと、
を備え、前記収容部は、前記光源に関連して配置されており、前記対象物の一部分が前記収容部に置かれた場合に、前記光源が作動して前記光源からの光が前記対象物の一部分に導かれるようになっていることを特徴とする装置。

【請求項 2】 前記多色光源が、前記電力インタフェースを介して前記外部の安定化電源に接続されることを特徴とする請求項 1 に記載の装置。

【請求項 3】 前記装置が、前記外部コンピュータと組み合わせて設けられ、前記外部コンピュータが、前記小型測定装置の少なくとも 1 つの機能を制御し、前記コンピュータが、前記測定信号を受信するための手段を含むことを特徴とする請求項 1 に記載の装置。

【請求項 4】 前記コンピュータと通信するために前記測定信号をデジタル測定信号に変換するための、アナログーデジタル変換器を更に備えることを特徴とする請求項 3 に記載の装置。

【請求項 5】 前記外部コンピュータが、複数の測定値に関する複数の前記測定信号を格納するためのメモリ、記憶装置、及びソフトウェア手段を含むこと

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を特徴とする請求項 3 に記載の装置。

【請求項 6】 前記外部コンピュータが、前記装置から前記コンピュータによって受信された測定信号に対応する投薬量情報を格納、検索、及び表示するためのメモリ、記憶装置、及びソフトウェア手段を含むことを特徴とする請求項 3 に記載の装置。

【請求項 7】 前記外部安定化電源が、前記外部コンピュータによって提供されることを特徴とする請求項 3 に記載の装置。

【請求項 8】 前記収容部が、外部光を低減するために、密接に位置合わせして前記対象物の一部分を収容するように成形されていることを特徴とする請求項 1 に記載の装置。

【請求項 9】 前記収容部に収容される対象物の一部分が人間の指であり、前記装置が、人間の手を収容するようになった開口部を有することを特徴とする、請求項 9 に記載の装置。

【請求項 10】 前記ハウジング開口部にハンド支持部を更に備え、前記ハンド支持部は、前記開口部の寸法を変更できるよう調整可能であることを特徴とする請求項 9 に記載の装置。

【請求項 11】 前記ハンド支持部が、人間の手のひらを収容し、前記開口部の上部が、人間の手の輪郭にほぼ一致するように湾曲していることを特徴とする請求項 10 に記載の方法。

(4) 003-508104 (P2003-508104A)

【発明の詳細な説明】

【0001】

(技術分野)

本発明は、血液成分の濃度レベルを非破壊的に測定するための小型装置に関する。本装置は、コンピュータと対話するための通信インタフェースを備える。

【0002】

(背景技術)

血液成分を測定する破壊的手法は一般的な用法である。これらの手法は苦痛を伴い、危険な場合があり、処置に経費がかかる。通常の手順は、静脈から血液試料を採取して、次に、各々の成分を別々に測定するための多数の化学的手順を用いて、この試料を医療研究所で検査するようになっている。もしくは、在宅グルコース検査は、指穿刺を用いて酵素ベースの半透膜試験片に斑点をつけ、それを所定時間反応させ、次に、目視による標準色チャートとの色比較に基づいて、又はより正確で明白な分光分析（例えば、いくつかの波長における反射率の測定及び比較による）に基づいてインシュリン投与が行なわれる。破壊的手法を用いる場合、感染する危険があり患者に発疹が出る場合もある。

【0003】

また、患者の血液成分の濃度を非破壊的にモニタするための装置も知られている。この装置は、体から放出されるガス成分の濃度、発汗中に含まれる濃度、又は、涙、唾液、又は尿の試料等の体液中に含まれる濃度のいずれかを外部で測定するのに用いられ、もしくは、血液成分は、耳朶又は指等の患者の身体の一部を通過する放射光を用いて測定される。

【0004】

最近開発され特許になっている非破壊的方法及び装置は、米国特許第5,361,758号に記載されており、1つの特定成分の濃度レベルをモニタするための、もしくは、同時に幾つかの異なる成分の濃度レベルを測定するための方法及び装置が開示されており、この方法及び装置では、非常に正確に、破壊的手法に比べて好都合に、短時間で結果が得られる。

【0005】

!(5) 003-508104 (P2003-508104A)

特に、米国特許第5,361,758号に開示される装置及び方法は、人間又は動物の生体の血液及び組織成分の濃度レベルを、近赤外線帯域の波長の広域スペクトルにわたる光を発する多色光源を用いて測定する。光は、指、耳朶、又は身体の他の部分等の、被験者の一部を通過するか、又はそこから反射する。次に、光は、回折格子又はプリズムを用いて種々の成分に分けられ、近赤外線帯域は、リニアアレイ検出器に集光される。マイクロプロセッサは、アレイ検出器の出力を用いて、運ばれてきた光（散乱光、及び透過光の場合もある）を測定し、等価吸光度を計算し、等価吸光度の2階導関数を計算する。モニタされる各々の成分に対する較正式を用いて、2階導関数測定値をその成分に関する濃度レベルに変換する。この装置は、グルコース、コレステロール、アルコール、血液ガス、及び種々のイオン等の、種々の血液及び組織成分の濃度レベルの測定のために用いることができる。

【0006】

米国特許第5,361,758号に説明されているような非破壊的モニタ装置に用いる指収容部は、米国特許第5,429,128号に開示されている。米国特許第5,429,128号に開示された指収容部は、ユーザの指を収容するための溝部を有している。この溝部は光の出入り口を有しており、光源から光は、溝部に置かれた指を略垂直な方向に通過することができる。外部の光は遮蔽されており、指はバネ式ローラーによって正しい位置に保持される。収容部は検出手段を有しており、指が溝部の正しい位置にあること判定するようになっている。

【0007】

米国特許第5,361,758号及び第5,429,128号に開示された方法及び装置は、血液又は組織中の既知の成分の濃度をモニタするための、著しく改善された有効な非破壊的手法を提供するが、小型で、効率的で持ち運びでき、安定性が高く、熱に起因する問題に対して影響を受けにくい装置に対する要求が依然としてある。

【0008】

(発明の開示)

!(6) 003-508104 (P2003-508104A)

本発明の目的は、血液成分の濃度レベルを非破壊的にモニタするための装置であって、小型で効率的であり、安定性が高く熱に対して影響を受けにくい装置を提供することにある。本装置は、コンピュータと対話するための通信インタフェースを含み、外部の安定化電源から電力が供給される。

【 0 0 0 9 】

1つの態様において、本発明は、人間又は動物等の生体対象物の血液及び組織成分の濃度レベルを非破壊的に測定するための測定装置であって、

(a) 近赤外線帯域における光の広域スペクトル及び隣接可視光を発する多色光源と、

(b) 生体対象物の一部を収容するよう成形された収容部と、

(c) 光が対象物の一部分に導かれた後に、広域スペクトルにわたる連続波長を集める受光体と、

(d) 集めた光を、該集めた光の成分波長の分光スペクトルに分光するように、受光部に接続される分光手段と、

(e) 分光スペクトルからの吸光度測定値を取得して測定信号を生成するように、分光手段へ接続される光検出器と、

(f) 測定信号を外部コンピュータへ伝達するように、コンピュータに接続可能な通信インタフェースと、

(g) 外部の安定化電源に接続可能な電力インタフェースと、
を備え、収容部は、光源に関連して配置されており、対象物の一部分が収容部に置かれた場合に、光源が作動可能になり光源からの光が対象物の一部分に導かれるようになっていることを特徴とする装置である。

【 0 0 1 0 】

多色光源は、電力インタフェースを介して外部の安定化電源に接続されることが好ましい。

外部コンピュータは、小型測定装置の少なくとも1つの機能を制御し、該コンピュータが測定信号を受信するための手段を含むことが好ましい。

本装置は、コンピュータと通信するために、測定信号をデジタル測定信号に変換するためのアナログーデジタル変換器を更に備えることが好ましい。

!(7) 003-508104 (P2003-508104A)

【 0 0 1 1 】

外部コンピュータは、複数の測定値に関する複数の測定信号を格納するためのメモリ、記憶装置、及びソフトウェア手段を含むことが好ましい。

外部コンピュータは、該コンピュータによって受信される、装置からの測定信号に対応する投薬量情報を格納、検索、及び表示するためのメモリ、記憶装置、及びソフトウェア手段を含むことが好ましい。

外部安定化電源は、外部コンピュータによって提供されることが好ましい。

本発明のより良い理解のため、そして効果がどのようにして実現されるかをより明確にするため、本発明の好適な実施形態を例示的に示す添付図面を参照されたい。

【 0 0 1 2 】

(発明を実施するための最良の形態)

前述のように、本発明は、血液成分の濃度レベルを非破壊的に測定するための小型装置に関する。

本発明に用いる非破壊的測定手法の基本的な作動原理は、米国特許第5, 361, 758号に示されており、その開示内容は、引用によって本明細書に組み込まれている。

【 0 0 1 3 】

米国特許第5, 361, 758号は、人間の組織が入射光に対して基本的に透明であり、結果的に十分な光の透過が可能で正確に定量分析ができるので、電磁スペクトルの近赤外線帯域が生体内診断用途に特に好適であることを開示している。

【 0 0 1 4 】

図1に示すように、血液及び組織成分の濃度レベルを連続的にモニタするための従来型の非破壊的装置は多色光源を備えている。米国特許第5, 361, 758号は、光源が、近赤外線スペクトルの光を含む非常に広い帯域幅にわたる光を発し得ることを開示している。(本出願人は、米国特許第5, 361, 758号が示す範囲の外側の隣接可視光も同様に生体内診断用途のための情報を与えることを認めている)。光源からの光は、最初に、レンズの集合体であり光を細い平

(8) 003-508104 (P2003-508104A)

行ビームに集中させて収容部に導くコリメータを通過する。収容部は、例えば人間の指又は耳等の被験者の一部分を収容するように成形されている。光は指又は耳の上に導かれ、指又は耳によって散乱して減衰する。散乱して減衰した光はレンズによって集光され、スリットを通過して回折手段に導かれる。回折格子であることが好ましい回折手段は、ホログラフィック法で製造できる。回折格子からの光は、その成分波長に分光され、光はリニアアレイ検出器の縦方向に沿って当たる。アレイ検出器は、マイクロプロセッサにより電氣的に走査され、収容部内の組織を通過した、又は組織から反射した各々の波長に関する光の強度を測定するための一連の光電素子を有している。検出器は、マイクロプロセッサに接続されており、出力スペクトルを生成し、マイクロプロセッサを用いて測定値を解析して、最終的には、測定された各々の濃度レベルに関する測定結果を生成する。測定結果は、ディスプレイに表示でき、及び／又はプリンタで印刷することができる。ユーザは、キーボードから装置を制御することができ、例えば、測定する特定の成分を指定できる。タイミング及び制御はマイクロプロセッサによって起動され、装置を制御して、例えば、測定回数と測定時期とを決定する。

【 0 0 1 5 】

米国特許第 5, 3 6 1, 7 5 8 号において、多色光源は、タングステナーハロゲン電球であってもよく、例えば、D C 電源等の安定化電源やバッテリーから電力が供給される。(本出願人は、放射光の光ルミネセンス源も使用できることを認めている)。多色光源は、タングステナーハロゲンランプであってもよく、又は近赤外線帯域(及び、本出願人が認めている隣接可視光線)の放射光を発するように選択された L E D 集合体又は他の光源であってもよい。光源を作動させた後に、光が受光部を通過して、選択波長における一連の測定値を取得することにより検出器によって測定されると、走査検出器は読み取られることに留意されたい。

【 0 0 1 6 】

米国特許第 5, 3 6 1, 7 5 8 号に開示されたシステムにおいて、マイクロプロセッサ制御装置は、検出脈拍が発生した場合にのみリニアアレイ検出器を起動して走査し、受光部を通過した後の光に関する全スペクトル測定値を取得する。

!(9) 003-508104 (P2003-508104A)

走査は、選択された波長に他の脈拍が検出されると停止する。すなわち、指、耳、又は人の他の部分の血圧が一定レベルにある場合にのみ測定値が取得される。

【 0 0 1 7 】

これに対し、本発明においては、測定値は脈拍の所定のフェーズにわたって取得されるか、又は幾つかの脈拍にわたって取得され、測定期間にわたって得られた信号の平均値が計算される。

【 0 0 1 8 】

米国特許第5, 361, 758号には、他の変形例として、装置が被験者の脈拍に関係なく全ての測定値を取得できることが説明されている。マイクロプロセッサは、各々の脈拍の間に取得した測定値を選択して、濃度レベルの算定を選択した測定値に基づいて行うように、コンピュータソフトウェアによって制御できる。更に別の変形例において、結果のベースとなる測定値は、複数の脈拍の間に取得できる。

【 0 0 1 9 】

米国特許第5, 361, 758号には、収容部が外部の光を遮蔽するための手段を備えていることが説明されている。例えば、光が通過する人間の一部分が指である場合、収容部は、指の形状と同様であるがそれよりも大きな矩形形状である。収容部で外部の光を遮蔽する手段は、収容部の入口を取り囲む可撓性リングである。指を挿入する場合、可撓性リングは、指が収容部に挿入された際に指の周りをシールする。収容部の表面を含む装置内部の全ての表面は、迷光を最小にするよう非反射性になっている。(シールを形成する可撓性リングは随意的であり、本発明では使用しない。しかし、以下で詳細に説明するように、測定値は、迷光を最小にするように取得されている。)

【 0 0 2 0 】

最後に、米国特許第5, 361, 758号は、指収容部に適切に配置された被験者の指に関する測定値を取得した後、入射光に関する測定値の参照セットを取得することが開示されており、この入射光は、収容部に被験者の何れの部分も接触していない場合に装置に発生する光である。次に、2つの測定値の比率を計算する。

(註 0) 103-508104 (P2003-508104A)

【 0 0 2 1 】

前記及び米国特許第 5, 3 6 1, 7 5 8 号に詳細に開示されている非破壊的モニタ装置の作動原理に基づいて、血液成分の濃度レベルを非破壊的にモニタするための新規な改良された小型装置は、図 2 に符号 1 0 で示されている。図 2 は、計器カバー又はハウジング 2 0 と、ハンド支持部 2 0 0 とを備える装置 1 0 の外側斜視図を示し、ユーザの血液又は組織の測定を行なうために、ユーザの手が挿入される開口部 1 1 が示されている。オプション部品の脚 2 1 0 により、装置 1 0 は平面上で正しい位置に配置される。

【 0 0 2 2 】

図 3 A から図 3 C、及び図 1 を参照すると、多色光源が設けられており、ランプハウジング又は反射器 9 4 (図 3 A 及び 3 B) 内のランプ 6 1 (図 3 C) を含むことができる。この光源又は図 3 A 及び図 3 B のランプ 9 1 は、前述のように近赤外線帯域及び更に隣接可視光を含む、広い帯域幅にわたる光を発生することができる。

【 0 0 2 3 】

米国特許第 5, 3 6 1, 7 5 8 号は、多色光源からの光を細い平行ビームに集光するための一連のレンズを用いるコリメータ (図 1) の使用を開示しているが、本発明では、多色光源又はランプ 9 1 からの光を反射して集光するための楕円反射器 9 4 を使用する。熱反射フィルタ 9 5 は、ランプ 9 1 から発生する熱を抑えるために楕円反射器 9 4 に設けられている。

【 0 0 2 4 】

更に図 3 A から図 3 C を参照すると、多位置形シャッタ 1 0 1 は、ランプ 9 1 と第 1 の光ガイド 1 2 0 との間に設けられており、第 1 の光ガイドに入る光を更に制御するようになっており、又は第 1 の光ガイドに入る光を迂過、減衰、又は遮蔽するようになっている。ステッピングモータ 1 0 0 は、多位置形シャッタ 1 0 1 を複数の回転位置の 1 つに回転させるために設けられている。1 つの位置において、多位置形シャッタ 1 0 1 は開口部 1 0 2 を提供して、光が楕円反射器によって第 1 の光ガイド 1 2 0 に集光されるようにする。他の位置において、複数の非常に小さな孔 1 0 3 が提供され、光源 9 1 からの光の一部が第 1 の光ガイド

(註1) 103-508104 (P2003-508104A)

120に入るようにする。更に別の位置において、フィルタ104が提供され、光源91から第1の光ガイド120に入る光を減衰させる。更に別の位置105において、多位置形シャッタ101は、光源91からの光を完全に遮蔽する。第1の光ガイド120に入る光を減衰又は他の方法で制御する他の種々の手段を多位置形シャッタ101に設けてもよい。

【0025】

更に図3Aないし図3Cを参照すると、第1の光ガイド120は、光ビームを指収容部70、140に導く。指収容部70、140の作動は、米国特許第5,429,128号に詳細に説明されており、本明細書に引用によって組み込まれている。米国特許第5,429,128号に開示されるように、指収容部70、140は、ユーザの指を溝部内に収容し、第1の光ガイドによって導かれる光ビームは、指収容部70、140内に挿入された指に対して略垂直に方向付けされる。米国特許第5,429,128号で開示され、前述したように、指収容部70、140は、指が溝部内に適切に置かれた場合を判定するための検知手段を含み、受光部(図1)が受信する信号を妨害する外部光を遮蔽するよう機能する。

【0026】

受光部(図1)に入る外部光の量をさらに低減するため、装置カバー20は指収容部及び装置ハウジング20、30内部の他の構成要素を実質的に覆うように設計されている。図2を参照すると、ハンド支持部200は、異なる大きさの手に適応させるよう開口部11の寸法を調節するために、好ましくは垂直方向に調節できることが好ましい。また、開口部11の上端は、人間の手の輪郭にほぼ適合するように成形してもよく、ハウジング20に入る外部の光は最小限となる。挿入された手の形状に上手く適合するように、開口部11の端部を若干可撓性としてよいことを理解されたい。

【0027】

指収容部70、140を通過する光は、受光部(図1)により受光され、受光部は、図3A及び図3Bにおいて第2の光ガイド130を備え、光ガイド130は、光を光ガイドアダプタ170及び分光器180に導く。次に、光は、定温式及び／又は冷却式光検出器アレイ組立体190によって検出され、組立体190

(註2) 103-508104 (P2003-508104A)

は、光検出器アレイ191と、熱電冷却器を制御するための電子装置192A及び光検出器アレイ191により受信された信号をデジタル化するための電子装置192Bと、放熱を行う熱電冷却器を含むヒートシンク193とを備える。

【0028】

光検出器アレイ組立体190の電子装置は、光検出器アレイ190が受信した光信号をコンピュータに伝送するためのアナログーデジタル変換を行うことが好ましい。アナログ信号は電磁妨害を受けやすいので、アナログ信号を処理及び変換のためにコンピュータへ送ることは好ましくない。前述のように、図3A及び図3Bに示して説明した（及び図1にブロック図の形式で示す）装置10は、最適に機能するための安定した作動条件を必要とする。装置10の安定性に重要な1つの構成要素は、大きな電力蓄積を有する安定化電源である。

【0029】

従来の装置では、このような電源は一般的に装置内に設けられており、電源及び他の内部構成要素が発生する熱は、装置の安定性と精度に影響を及ぼす場合もあった。

【0030】

安定性が改善された、小型で高性能な装置を提供するために、図2から図4に示す装置10は、装置10の外部にある電源によって作動する。装置10は、コンピュータ300（図4）と接続するように設計されているので、装置10はコンピュータ電源310から電力を得ることが好ましい。装置10に対して安定したクリーンな電源を供給するため、コンピュータ電源と装置10との間に電力調整器311を設けてもよい。

【0031】

図3Aから図3Cを参照すると、装置内部で最も多くの熱を発生する構成要素は、ランプハウジング90内のランプである。ランプ及びランプハウジング90が発生する熱の影響を最小限にするために、ランプ熱遮蔽部50は、ランプハウジング90と、電子装置40、分光器180及び光検出器アレイ190を含む装置内部の他の構成要素との間に設けられている。更に、多位置形シャッタ101を制御するための電子基板60も同様に、ランプ91に起因して多位置形シャッ

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タハウジング115から伝達される熱に対して電子装置40を遮蔽する。

【0032】

熱を発生するランプハウジング90を装置内部の他の構成要素から遮蔽すること、及び電源が装置の外部（好ましくはコンピュータ電源310）にあるように電源を取り去ることによって、好都合に、装置ハウジング内で発生する熱は著しく低減する。ハウジング20、30内で発生する熱は、光検出器アレイ190に設けられたヒートシンクによって放熱され、また、冷却ファン150、160及び排気口21によって装置ハウジング20、30から追い出される。

【0033】

ハウジング20、30内で熱の発生が著しく低減される結果として、及び装置内の電子回路における電子ノイズが低減される結果として、装置10内で低出力の光源を使用できる。すなわち、光源として使用されるランプ（タングステンハロゲンランプ）は、内部電源を有する装置と比較して、低出力で同等の測定感度レベルを維持できる（電子回路内におけるノイズが少ないため）。

【0034】

また、コンピュータ300（図4）を装置10と相互接続して、多数の制御機能を処理することによって、装置10内に必要とされる電子装置40は、基本制御及び通信機能に最小化できる。実際には、装置10は、コンピュータの周辺装置のように作動し、装置10の主要機能は、光源と受光部を提供し、次の処理のために、測定結果として生じる生データを提供することにある。

【0035】

好適な実施形態において、装置10は専用コンピュータインタフェースカード320を用いてコンピュータと相互接続される。例えば、コンピュータインタフェースカード320は、現在利用可能な殆どのパーソナルコンピュータシステムに対して一般的である業界基準PCI（Peripheral Circuit Interconnect）バス、又はISA（Industry Standard Architecture）バス、又は将来コンピュータインターフェースのために開発されるであろう、他のバスと相互接続するように作ることができる。携帯型ラップトップに使用するために、適切な専用コンピュータインタ

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フェースカードをP C M C I A業界基準に合せて開発してもよい。コンピュータインタフェースカード320は、装置10からのアナログデータを受信して、コンピュータ300による処理のためにアナログデータをデジタル信号に変換してもよい。

【0036】

パラレル又はシリアルポート、S C S I及びU S Bポート等の他の業界基準インタフェースを通して装置10に接続することも可能であるが、そのようなオプション部品は、装置ハウジング20、30内部に配置される付加的な電子装置を必要とするので、装置10内部での熱の発生を増加させる。それにもかかわらず、パラレル、シリアル、S C S I、又はU S Bポートへの接続は、コンピュータヘカードを取り付ける必要がなくなるという利点をもたらす。

【0037】

前述のように、装置10をコンピュータ300へ相互接続すると、メモリ330及びマイクロプロセッサ340で実行され、随意的にコンピュータ300の記憶装置380に格納されているソフトウェア手段を用いて装置10を制御することが可能になる。更に、ソフトウェア手段は、装置10を操作するための段階的な指示を含む、適切なディスプレイ350上のグラフィカル・ユーザ・インターフェースをユーザに提供できる。

【0038】

また、ソフトウェア手段は、装置10によって収集されたデータの受信と解析を制御でき、測定結果を図示的にコンピュータディスプレイ350に表示し、又は随意的に測定結果をプリンタ355で印刷することができる。一連の結果は、次の処理又は呼び出しのために記憶装置380に格納できる。装置10は、他の多くの可能性のある入力装置のなかで、キーボード360又はマウス370等の入力装置を用いて制御できる。

【0039】

要約すると、装置10を、光源を提供して、指収容部70、140に置かれた指を通過する光を測定するための基本的な構成要素にほぼ限定することによって、装置10の寸法及びコストが著しく低減される。また、装置内で発生する熱が

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著しく低減されることによって冷却の必要性が少なくなり、装置10は熱の問題に影響されなくなり、装置の安定性及び精度が改善される。また、コンピュータ300に制御インタフェース及び解析を移すことによって、コンピュータ300の処理能力が、ユーザインタフェースを強化して装置10によって収集された生データの解析を強化するために使用される。

【0040】

本発明による装置の1つの実施形態を示して説明したが、請求項によって定義される本発明の範囲から逸脱することなく、種々の変更及び修正が可能であることを理解されたい。

【図面の簡単な説明】

【図1】

血液成分の濃度レベルを非破壊的にモニタするための装置の種々の構成要素の関係を示すブロック図である。

【図2】

本発明による装置の1つの実施形態を示す斜視図である。

【図3A】

図2の装置の他の斜視図であって装置内部の構成要素の一部を示す。

【図3B】

図2の装置の分解組立図であって、図3Aの装置内部の構成要素を示す。

【図3C】

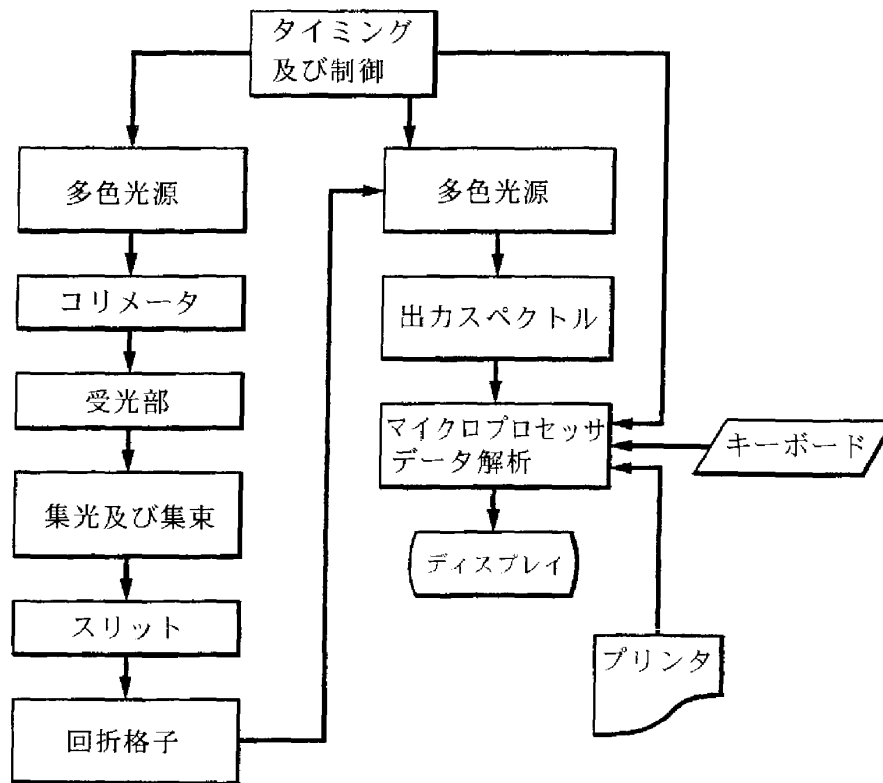
図3A及び図3Bに示された装置の主要構成要素の一部の概略図を示す。

【図4】

図2、図3Aから図3Cの装置と、コンピュータシステムとの間の関係を示すブロック図である。

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【図1】



従来技術

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【圖2】

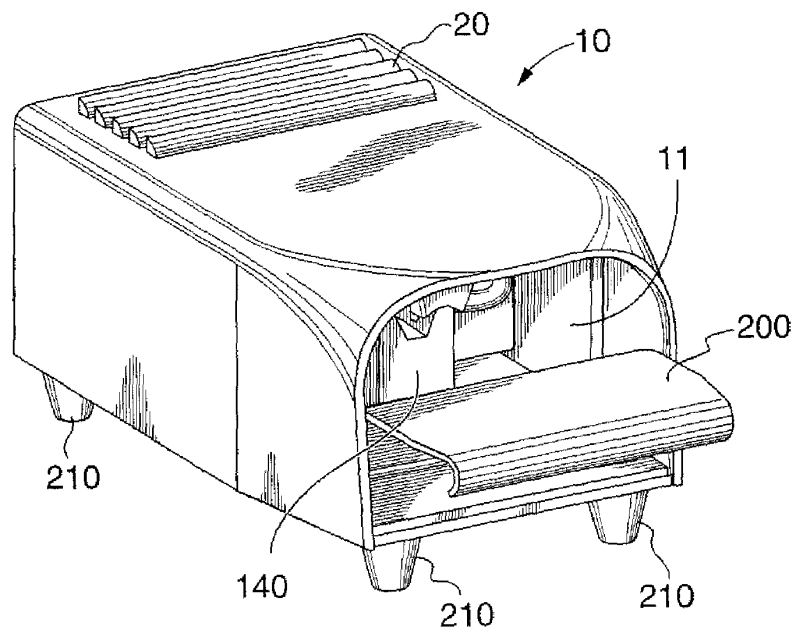


FIGURE 2

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【圖3A】

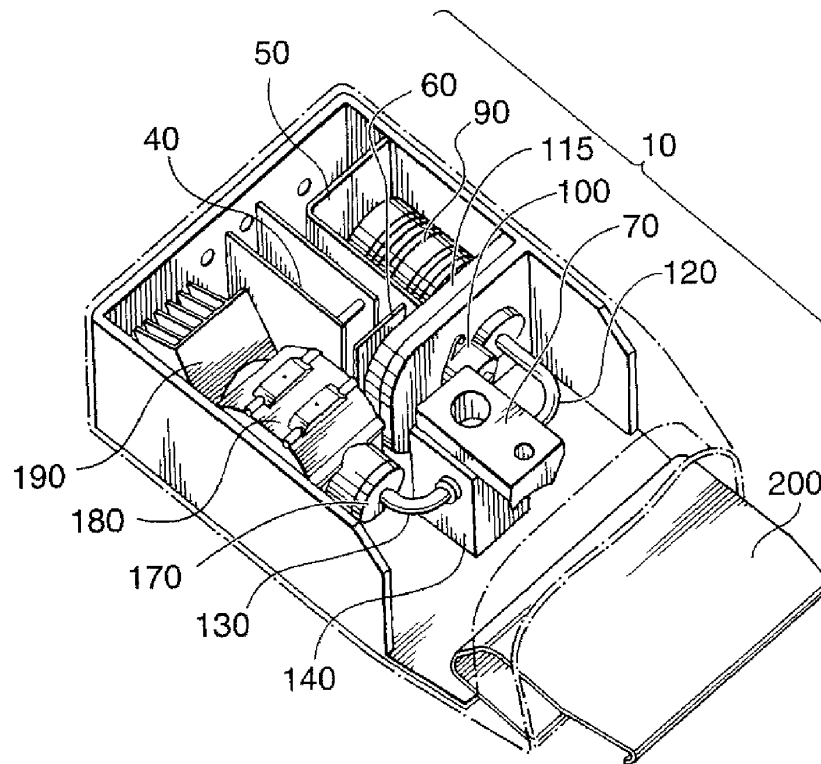


FIGURE 3A

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【図3B】

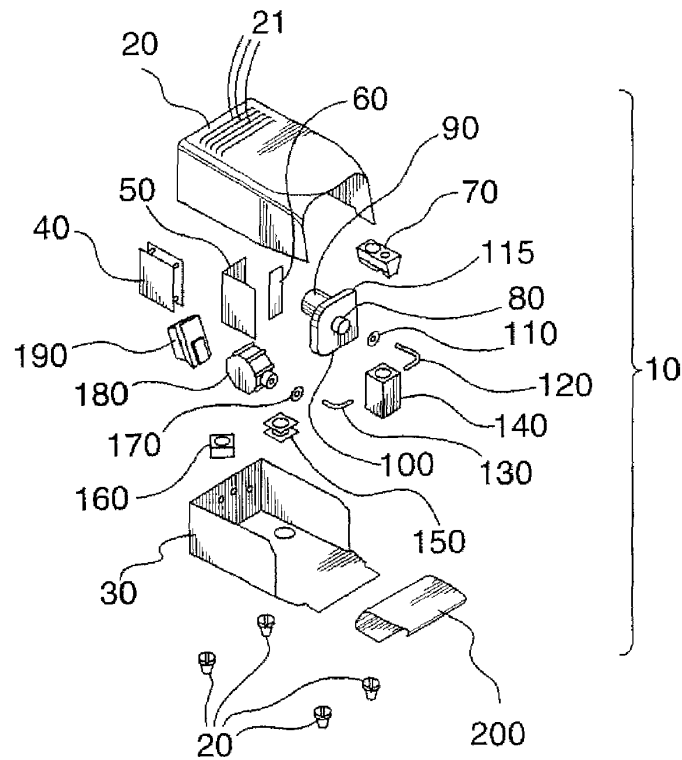


FIGURE 3B

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【図3C】

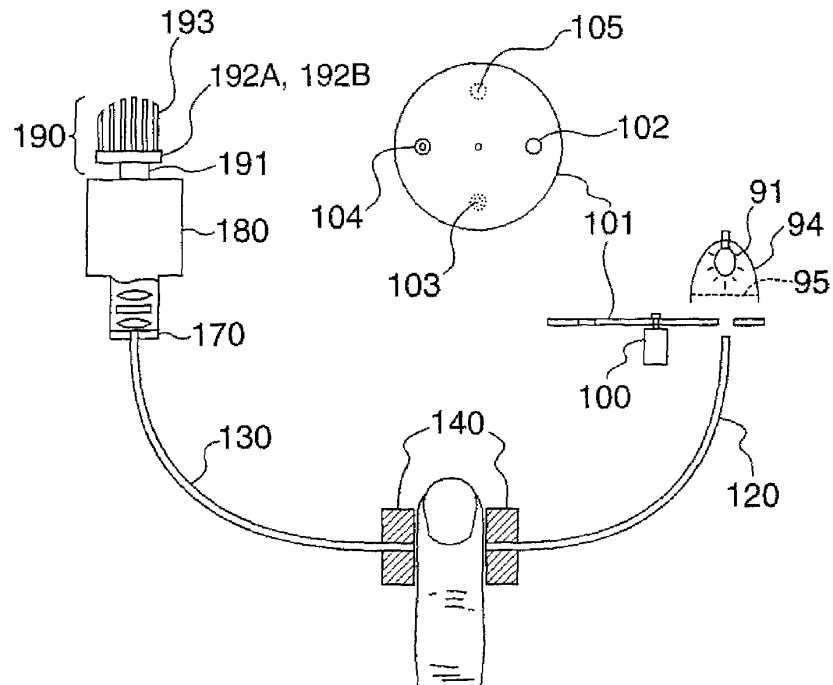


FIGURE 3C

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【図4】

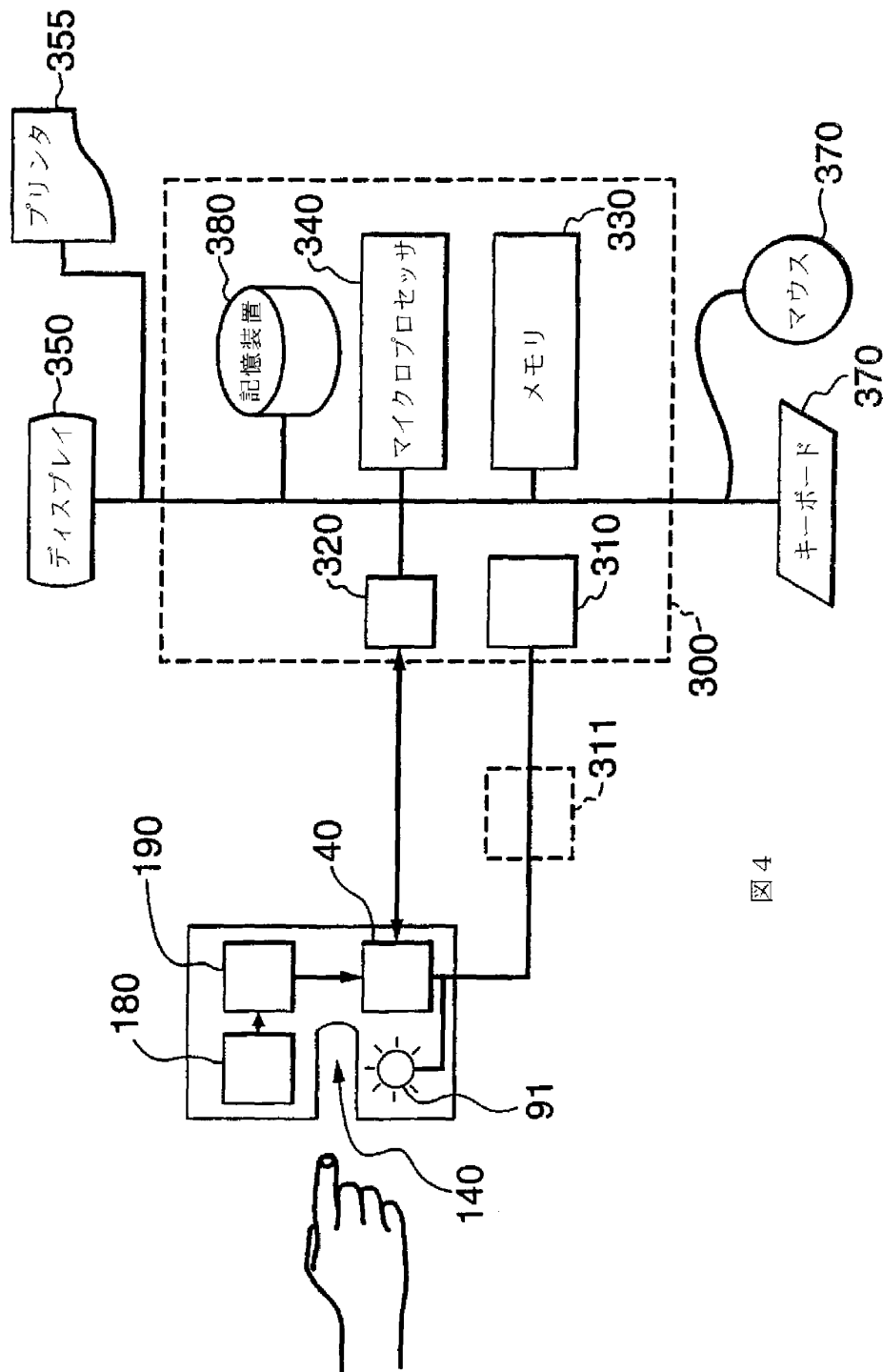


図4

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【国際調査報告】

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B5/00 G01N21/31 G01N21/35		International Application No. PCT/CA 00/01004
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B G01N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 361 758 A (HALL JEFFREY W ET AL) 8 November 1994 (1994-11-08) cited in the application column 3, line 52 -column 4, line 58; figure 1	1,5,6,8, 9
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents: *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art *Z* document member of the same patent family		
Date of the actual completion of the international search: 28 December 2000		Date of mailing of the international search report: 05/01/2001
Name and mailing address of the ISA European Patent Office, P.B. 5516 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 epo.nl. Fax: (+31-70) 340-3016		Authorized officer: Meyer, F

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INTERNATIONAL SEARCH REPORT

International Application No.
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C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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ード 832

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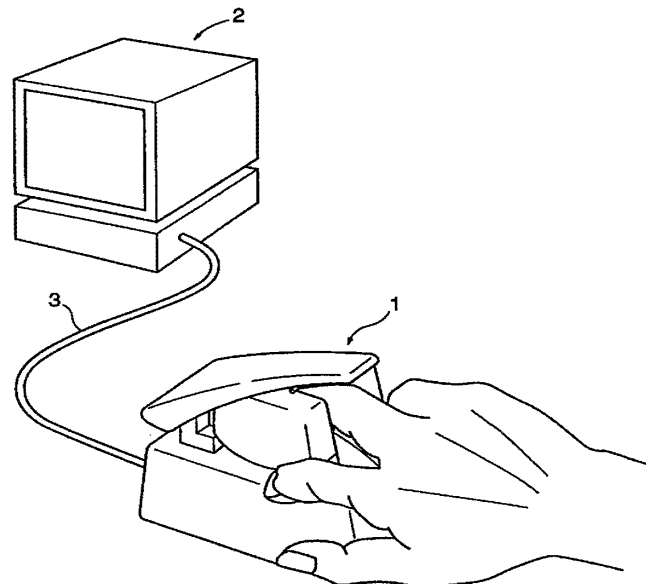
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特許協力条約に基づいて公開された国際出願

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(21) 国際出願番号 PCT/JP98/02875 (22) 国際出願日 1998年6月24日(24.06.98) (30) 優先権データ 特願平9/172216 1997年6月27日(27.06.97) JP 特願平9/331924 1997年12月2日(02.12.97) JP (71) 出願人 (米国を除くすべての指定国について) 東亜医用電子株式会社 (TOA MEDICAL ELECTRONICS CO., LTD.)[JP/JP] 〒650-0046 兵庫県神戸市中央区港島中町7丁目2番地の1 Hyogo, (JP) (72) 発明者 ; および (75) 発明者 / 出願人 (米国についてのみ) 木村六三郎(KIMURA, Rokusaburo)[JP/JP] 〒657-0064 兵庫県神戸市灘区山田町1丁目2番14号 Hyogo, (JP) 浅野 薫(ASANO, Kaoru)[JP/JP] 〒651-2136 兵庫県神戸市西区中野1丁目17番19号 Hyogo, (JP) 楠澤英夫(KUSUZAWA, Hideo)[JP/JP] 〒651-1513 兵庫県神戸市北区鹿の子台北町4丁目8番14号 Hyogo, (JP)	(21) 国際出願番号 PCT/JP98/02875 (22) 国際出願日 1998年6月24日(24.06.98) (30) 優先権データ 特願平9/172216 1997年6月27日(27.06.97) JP 特願平9/331924 1997年12月2日(02.12.97) JP (71) 出願人 (米国を除くすべての指定国について) 東亜医用電子株式会社 (TOA MEDICAL ELECTRONICS CO., LTD.)[JP/JP] 〒650-0046 兵庫県神戸市中央区港島中町7丁目2番地の1 Hyogo, (JP) (72) 発明者 ; および (75) 発明者 / 出願人 (米国についてのみ) 木村六三郎(KIMURA, Rokusaburo)[JP/JP] 〒657-0064 兵庫県神戸市灘区山田町1丁目2番14号 Hyogo, (JP) 浅野 薫(ASANO, Kaoru)[JP/JP] 〒651-2136 兵庫県神戸市西区中野1丁目17番19号 Hyogo, (JP) 楠澤英夫(KUSUZAWA, Hideo)[JP/JP] 〒651-1513 兵庫県神戸市北区鹿の子台北町4丁目8番14号 Hyogo, (JP)	
(54)Title: LIVING BODY INSPECTING APPARATUS AND NONINVASIVE BLOOD ANALYZER USING THE SAME (54)発明の名称 生体検査装置およびそれを用いた非侵襲血液分析装置 (57) Abstract An object of this invention is to obtain inspection results of a high accuracy and a high reproducibility by fixing a part of a living body of a subject naturally and stably. An apparatus for imaging a living body, provided with a base on which a part of a living body of a subject is placed, two side wall members capable of holding from both sides the part placed on the base of the living body, a light source for supplying light to the living body held by the base and side wall members, and a light receiving member for detecting optical information from the part of living body which receives the light; and a noninvasive living body inspection apparatus provided with the above apparatus for imaging a living body wherein the light receiving member comprises imaging elements, and an analyzer adapted to analyze images of the tissues including blood vessels obtained by the imaging elements, and process the information on the blood flowing in the blood vessels.		



(57)要約

測定対象の生体の一部を無理なく安定して固定し、正確で再現性のよい検査結果を得ることを課題とする。

検査対象とする生体の一部を載置する基台と、載置された生体の一部を両側から挟持可能な2つの側壁部材と、基台及び側壁部材により保持された生体に光を供給する光源部と、光を受けた生体の一部から光学的情報を検出する受光部とを備えてなる生体撮像装置、および受光部が撮像素子からなる上記生体撮像装置と、撮像素子によって得られる血管を含む組織の画像を解析してその血管を流れる血液に関する情報を算出する解析部とを備える非侵襲生体検査装置。

PCTに基づいて公開される国際出願のパンフレット第一頁に掲載されたPCT加盟国を同定するために使用されるコード(参考情報)

AL	アルバニア	FI	フィンランド	LK	スリ・ランカ	SI	スロヴェニア
AM	アルメニア	FR	フランス	LR	リベリア	SK	スロヴァキア
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BR	ブラジル	HR	クロアチア	ML	マリ	UA	ウクライナ
BY	ベラルーシ	HU	ハンガリー	MN	モンゴル	UG	ウガンダ
CA	カナダ	ID	インドネシア	MR	モーリタニア	US	米国
CF	中央アフリカ	IE	アイルランド	MW	マラウイ	UZ	ウズベキスタン
CG	コンゴ	IL	イスラエル	MX	メキシコ	VN	ヴェトナム
CH	スイス	IN	インド	NE	ニジェール	YU	ユーゴスラビア
CI	コートジボアール	IS	アイスランド	NL	オランダ	ZW	ジンバブエ
CM	カメルーン	IT	イタリア	NO	ノルウェー		
CN	中国	JP	日本	NZ	ニュージーランド		
CU	キューバ	KE	ケニア	PL	ポーランド		
CY	キプロス	KG	キルギスタン	PT	ポルトガル		
CZ	チェコ	KP	北朝鮮	RO	ルーマニア		
DE	ドイツ	KR	韓国	RU	ロシア		
DK	デンマーク	KZ	カザフスタン	SD	スーダン		
EE	エストニア	LC	セントルシア	SE	スウェーデン		
ES	スペイン	LI	リヒテンシュタイン	SG	シンガポール		

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明 細 書

生体検査装置およびそれを用いた非侵襲血液分析装置

5 技術分野

この発明は、生体検査装置およびそれを用いた非侵襲血液分析装置に関し、とくに、生体の一部の血管を含む組織からの光学的情報を経皮的に検出する装置と、検出された光学的情報を分析して血液に関する情報、例えばヘモグロビン濃度やヘマト
10 クリットを得る装置に関する。

背景技術

この種の生体検査装置においては、ヒトの指を指受け装置の溝に受入れ、指をその輪郭が溝の断面形状になじむまでローラ
15 で押圧して変形させ、変形した指に光を照射してその透過光を検出するようにしたものが知られている（例えば、特表平6-503728号公報参照）。

しかしながら、このような従来の装置においては、指が溝内で直線状に引伸ばされると共に強く圧迫され、血管や組織が変
20 形してうっ血や虚血状態となるため、正常な状態の血管や組織からの光学情報を得ることができないという問題がある。

この発明は、このような事情を考慮してなされたもので、過度な矯正力や圧迫を加えることなく生体の一部を安定に保持して正常な光学情報を得ることが可能な生体検査装置とそれを用

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いた非侵襲血液分析装置を提供するものである。

発明の開示

この発明は、検査対象とする生体の一部を載置する基台と、
5 載置された生体の一部を両側から挟持可能な側壁部材と、基台
及び側壁部材により保持された生体に光を供給する光源部と、
光をうけた生体の一部から光学的情報を検出する受光部とを備
えてなる生体検査装置を提供するものである。

この生体検査装置において、基台は例えばヒトの手の掌とそ
10 の複数の指に適合する形態を有し、側壁部材はその複数の指の
内の 1 本の指を光源部と受光部に対して適正に位置決めする。

さらにこの発明は、受光部が撮像素子からなる生体検査装置
を提供するものである。さらにこの発明は生体検査装置の撮像
素子によって得られた血管を含む組織の画像を解析してその血
15 管を流れる血液に関する情報を算出する解析部と、算出された
情報を出力する出力部とを備える非侵襲生体検査装置を提供す
るものである。

図面の簡単な説明

20 図 1 は、この発明の第 1 実施例における検出部と解析部の構
成を示すブロック図である。

図 2 は、この発明の第 1 実施例における検出部と解析部の外
形を示す斜視図である。

図 3 は、この発明の第 1 実施例の検出部を示す斜視図である。

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図 4 は、この発明の第 1 実施例の検出部の平面図である。

図 5 は、この発明の第 1 実施例の検出部の正面図である。

図 6 は、この発明の第 1 実施例の検出部の側面図である。

図 7 は、この発明の第 1 実施例の検出部の背面図である。

5 図 8 は、この発明の第 1 実施例の検出部の図 4 における X - X 矢視断面図である。

図 9 は、この発明の第 1 実施例の検出部の図 4 における Y - Y 矢視断面図である。

10 図 10 は、この発明の第 1 実施例の検出部の図 4 における Z - Z 矢視断面図である。

図 11 は、この発明の第 1 実施例の検出部に用いるスプリングの斜視図である。

図 12 は、この発明の第 1 実施例における検出部と解析部の動作を示すフローチャートである。

15 図 13 は、この発明の第 1 実施例における解析領域の決定手順を示すフローチャートである。

図 14 は、この発明の第 1 実施例により得られる画像例を示す説明図である。

20 図 15 は、この発明の第 1 実施例により得られる画像例を示す説明図である。

図 16 は、この発明の第 1 実施例により得られる画像の濃度プロファイルを示す説明図である。

図 17 は、この発明の第 1 実施例により得られる画像の正規化された濃度プロファイルを示す説明図である。

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図 1 8 は、この発明の第 1 実施例の光源部の正面図である。

図 1 9 は、この発明の第 1 実施例により表示される表示例を示す説明図である。

図 2 0 は、この発明の第 1 実施例により表示されるの他の表示例を示す説明図である。

図 2 1 は、この発明の第 2 実施例の検出部を示す斜視図である。

図 2 2 は、この発明の第 2 実施例の検出部を示す側面図である。

10 図 2 3 は、この発明の第 2 実施例の検出部を示す平面図である。

図 2 4 は、この発明の第 2 実施例の検出部を示す正面図である。

15 図 2 5 は、この発明の第 2 実施例の検出部を示す背面図である。

図 2 6 は、この発明の第 2 実施例の検出部を示す底面図である。

図 2 7 は、この発明の第 2 実施例の検出部を示す縦断面図である。

20 図 2 8 は、この発明の第 2 実施例の検出部を示す要部切欠き側面図である。

図 2 9 は、図 2 8 の W - W 矢視断面図である。

図 3 0 は、この発明の第 2 実施例の検出部の動作を示す説明図である。

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図 3 1 は、この発明の第 2 実施例の検出部の動作を示す説明図である。

図 3 2 は、この発明の第 3 実施例の検出部と解析部の構成を示すブロック図である。

5 図 3 3 は、この発明の第 3 実施例の検出部と解析部の動作を示すフローチャートである。

図 3 4 は、この発明の第 3 実施例により得られる画像における平均輝度の判定領域を示す説明図である。

10 図 3 5 は、この発明の第 3 実施例により得られる画像において漏光像が存在する例を示す説明図である。

図 3 6 は、この発明の第 3 実施例により漏光像を検出する方法を示す説明図である。

図 3 7 は、この発明の第 3 実施例により得られる画像の輝度プロファイルの一例を示す説明図である。

15 図 3 8 は、この発明の第 3 実施例により得られる画像の輝度プロファイルの他の例を示す説明図である。

図 3 9 は、この発明の第 3 実施例により漏光像を検出する方法を示す説明図である。

20 図 4 0 は、この発明の第 3 実施例により得られる関節部分の画像例を示す説明図である。

図 4 1 はこの発明の第 3 実施例において関節部分を検索する領域の画素グループを示す説明図である。

図 4 2 はこの発明の第 3 実施例において関節部分を検索する領域の画素グループを示す説明図である。

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発明を実施するための最良の形態

この発明の生体検査装置において、生体とはヒト、うさぎ、イヌ、ネコ、ラット、マウスなどを含む哺乳動物であり、生体の一部とは生体から分離した組織ではなく、生体のありのままの組織の一部であり、例えばヒトでは手の指や足の指、他の動物では尾部などがあげられる。

この発明において、基台に載置された生体の一部は側壁部材によって両側から適度な圧力で弾性的に挟持されることが好ましい。これは生体の一部を余り強く締付けたり変形させて固定すると血管が圧迫されてうっ血状態や虚血状態を生じて正確な検査結果が得られないからである。また、生体の一部の太さが異なっても基台のセンターに安定して載置することができるからである。また、生体の一部をより自然な状態で基台に載置するために生体の一部を載置する基台は、載置される生体の一部の形態にその表面の少なくとも一部がフィットするように形成されるのが好ましい。

例えば検査対象とする生体の一部がヒトの手の指であるときには、基台が検査対象の指を含む複数の指とそれらの指を有する掌によって形成される曲面に適合可能な曲面からなる表面形状を有し、側壁部材はその複数の指と掌が上記曲面に適合するように基台上に載置されるとき検査対象の指を両側から挟むように基台から突出してなることが好ましい。さらに基台はその上面に検査対象の指を位置決めするための少なくとも1つの窪

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みを備えることが好ましく、3つの窪みを備えることがさらに好ましい。つまり複数の指をそれぞれ位置決めする窪みを基台上に併せて備えることにより、指と掌はさらに安定して基台上に載置される。

- 5 また、各側壁部材は、互いに接近して生体の一部を挟むように付勢されることが好ましい。

これは、例えば、両側側壁部材を互いに接近する方向に移動可能に支持する支持部材と、両側壁部材を互いに接近する方向に付勢する付勢部材を基台に備えることにより実現できる。

- 10 この場合、支持部材は、摺動機構又はヒンジ機構を有し、付勢部材はばねのような部材からなることが好ましい。

また、側壁部材は、生体の一部を挟持する状態において、その生体の一部を基台方向に押圧する力成分が生じるように付勢されることが好ましい。

- 15 検査対象とする生体の一部が動物の尾部である場合には、基台は尾部の形態にフィットする表面形状を有し、側壁部材も載置された尾部を変形や圧迫しない程度に挟持するものであることが好ましい。この場合、基台は尾部を位置決めする少なくとも1つの窪みを備えるとよい。

- 20 また、生体検査装置において、基台および側壁部材は、生体の一部大きさに応じて複数種類のサイズのことを準備しておくことができる。例えば、生体の一部がヒトの手の指の場合には、乳児用、子供用、大人用の3種類を準備することができる。その際、基台および側壁部材がその他の構成部材から容易に離

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脱可能に設置される構造であると好都合である。

光源部には、半導体レーザ（以下、LD）やLEDあるいはハロゲン光源などの光源が使用でき、直接生体の一部に照射してもよいし、ファイバーを介して照射してもよい。波長として
5 は、生体組織を透過し水に対する吸収が大きくない600～950nmの範囲にあることが好ましい。

受光部は、レンズなどの光学系とフォトダイオードやCCDなどの受光素子とから構成できる。

血管部分の濃度分布情報を詳細に得るためには、受光素子としてCCDなどの撮像素子を用いることが好ましい。CCDの
10 他にラインセンサーやフォトダイオード・アレイが使用できる。

また、フォトダイオード1個を血管を横切る方向に走査させて濃度分布情報を得ることもできる。

受光部の光学系は、受光素子としてCCDなどの撮像素子を用いる場合には単にTV用レンズ（例えばCOMICAR製 BD1214
15 D）だけを用いて構成してもよい。

この発明の装置は、カバー部材をさらに備え、そのカバー部材は側壁部材に挟持された生体の一部の上方を覆うようにしてもよい。この場合、光源部をカバー部材に設け、受光部を基台
20 の下方に設け、受光部を、光源から生体の一部を透過した光を基台に設けた開口を介して受光するように設置することができる。

また、この発明の非侵襲血液分析装置は、受光部が撮像素子からなる上記生体検査装置によって得られた血管を含む画像を

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解析してその血管を流れる血液に関する情報を算出する解析部を備えるが、ここで血液に関する情報とは、血液や血流に関する情報であって、具体的には血液成分濃度や血管径などである。

5 なお、上記解析部はパーソナルコンピュータで構成することができる。

この発明の非侵襲血液分析装置は、生体検査装置により得られた画像に基づいて生体の一部の基台に対する載置状態を判定する判定部と、判定された載置状態に基づく指示メッセージを出力する出力部とをさらに備えてもよい。

10 また、この発明の非侵襲血液分析装置は、得られた画像に基づいて光源部の光量を制御する光量制御部をさらに備えてもよい。

以下、図面に示す実施例に基づいてこの発明を詳述する。これによってこの発明が限定されるものではない。

15 第1実施例

図1はこの発明の生体検査装置を用いた非侵襲血液分析装置の第1実施例の構成を示すブロック図である。図1において、生体検査装置としての検出部1は、血管を含む生体の一部（ここではヒトの手の中指）を照明するための光源部11と、照明
20 された生体部分の光像（ここでは透過光像）を撮像する撮像部12を備える。すなわち、検出部1はここでは生体撮像装置である。

解析部2は、撮像部12が生体の一部を経時的に複数回撮像するとき、撮像された画像ごとにその画像における生体の一部

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の位置的特徴（ここでは、指の関節部分の輪郭におけるくぼみの座標）を抽出する特徴抽出部 3 1 と、抽出された各特徴を記憶する記憶部 3 2 と、各特徴を比較する比較部 3 3 と、比較結果に基づき複数の画像において同一血管部位を含む解析領域を設定する解析領域設定部 3 4 を備える。

さらに、解析部 2 は、撮像された画像について解析領域内の血管を直角に直線的に横切る部分の画像濃度分布を画像の濃度プロファイルとして抽出する抽出部 2 1 と、抽出された濃度プロファイルの形態的特徴を定量化する定量化部 2 2 と、定量化された特徴に基づいて血管径および血液の成分濃度などを演算する演算部 2 3 と、演算結果を記憶する記憶部 2 5 と、演算結果やモニタ画像を出力する出力部（C R T）2 4 を備える。

なお、入力部 3 5 はキーボードとマウスからなり、計測モードの設定や解析領域の初期設定、演算部 2 3 の演算条件の入力などを行う。また、解析部 2 はパーソナルコンピュータによって構成される。

図 2 は図 1 に示す装置の外観斜視図であり、検出部 1 と解析部 2 とは信号ケーブル 3 によって接続されている。

図 3 は検出部 1 を示す斜視図、図 4 ～図 7 は、それぞれ検出部 1 を示す平面図、正面図、側面図および背面図である。また、図 8 ～図 1 0 は、それぞれ図 4 における X - X, Y - Y, Z - Z 矢視断面図である。

これらの図において、基台部材 5 1 は、検査対象とする生体の一部としてのヒトの手の中指 F（図 8, 図 9）を載置する基

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台 5 2, 5 3 と、基台 5 2, 5 3 を支持する基板 5 4 を備える
(図 6)。基板 5 4 には基台 5 2, 5 3 に載置された中指 F (以下、指 F という) を両側から弾性的に挟持可能な 2 つの側壁部材 5 5, 5 6 が、基台 5 2, 5 3 を挟むように配置される
5 (図 9)。また、カバー部材 5 7 は、基台 5 2, 5 3 に載置される指 F の上方を覆うように設けられる (図 6)。また、基板 5 4 はハウジング 5 8 の上に固定される (図 6)。

カバー部材 5 7 は、カバー 5 7 a と、その下面に接着されたアーム 5 7 b を備える (図 8)。図 4 および図 7 に示すように、
10 アーム 5 7 b の一端は、アームホルダー 5 9 の突出部 5 9 a と 5 9 b との間にスプリング 6 0, 6 1 と共に挿入され、それらを貫通する頭付きシャフト 6 2 によって支持される。スプリング 6 0, 6 1 は図 1 1 に示すように線材をターンさせてその両端が 9 0 度をなすように製作されたものである。

15 突出部 5 9 a と 5 9 b との間にシャフト 6 2 によって装着されたスプリング 6 0, 6 1 は、図 6, 図 7 に示すように、その一端が 3 つのビス 6 3 によってアーム 5 7 b の両側面にそれぞれ固定され、その他端は、アームホルダ 5 9 の後面に係止される。スプリング 6 0, 6 1 は、図 6 に示す状態においては、各
20 両端が 9 0 度よりも大きい角度を形成し、アーム 5 7 b を矢印 A 1 方向に付勢する。また、シャフト 6 2 の先端には抜止め用カラー 6 4 が嵌入されている。

つまり、アーム 5 7 b とアームホルダー 5 9 とは、ヒンジ機構を構成し、アーム 5 7 b は図 6 に示すようにシャフト 6 2 を

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中心として矢印 A 1, A 2 方向に回動可能であると共に、スプリング 6 0, 6 1 の付勢力により常時矢印 A 1 の方向に付勢される。

一方、図 6, 図 1 0 に示すように、側壁部材 5 5, 5 6 の下面にそれぞれ突出する突出部 5 5 a, 5 5 b および 5 6 a, 5 6 b は、基板 5 4 にそれぞれ突出する突出部 5 4 a, 5 4 b および 5 4 c, 5 4 d の間に挿入され、それらを貫通する頭付シャフト 6 5, 6 6 によって支持される。また、シャフト 6 5, 6 6 の各先端には抜止め用カラー 6 5 a, 6 6 a が固定されている。

これによって、図 9 に示すように側壁部材 5 5 はシャフト 6 5 を中心に矢印 B 1, B 2 方向に、側壁部材 5 6 はシャフト 6 6 を中心に矢印 C 1, C 2 方向に回動可能となる。図 9 に示すように、コイルスプリング 6 7, 6 8 がそれぞれ側壁部材 5 5 の下面と基板 5 4 の上面との間、および側壁部材 5 6 の下面と基板 5 4 の上面との間に装着され、側壁部材 5 5 を矢印 B 1 方向に、側壁部材 5 6 を矢印 C 1 方向にそれぞれ付勢する。

また、光源部 1 1 は図 8 に示すようにアーム 5 7 b に形成された孔 5 7 c 内に設けられ、基台 5 2 と 5 3 との間の溝 6 9 を介してハウジング 5 8 に設置された撮像部 1 2 と互いに対向する。

また、溝 6 9 の上部開口部には指 F を支持すると共に光源部 1 1 からの光を透過させるガラス板 7 0 が基台 5 2 から 5 3 へ渡るように装着されている。図 4, 図 5 に示す 2 本のピン 5 7

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dはアーム 5 7 b の両側に突出し、指 F が挿入されないときにそれぞれ側壁部材 5 5, 5 6 の上面に係止する。

ここで、指 F が図 8 に示すように基台 5 2, 5 3 の上に載置されると、図 9 に示すように指 F の両側が側壁部材 5 5, 5 6 の側壁面によりほぼ均等な軽い力で押圧されると共に、指 F の上側がアーム 5 7 b によって軽く押圧される。これによって指 F は基台 5 2, 5 3 上に位置決めされる。

指 F が基台 5 2, 5 3 上に位置決めされると、光源部 1 1 が指 F を照明し、その透過光が撮像部 1 2 で受光される。撮像部 1 2 はレンズと C C D を備え、透過光による指 F の画像を撮像する。

ここで、図 8 に示すように、基台 5 2, 5 3 およびガラス板 7 0 は、指 F と接触する面が、指 F の自然の曲りにフィットするよう円弧状に形成されているので、指 F を載置したときに、指 F が不自然に引き伸ばされることや指の血管がうっ血したり虚血状態を生じることがない。

また、図 9 に示すように、側壁部材 5 5, 5 6 の指 F に接触する対向面は、互いに平行ではなく上部が下部に比べて狭くなるようなテーパ（傾き）を有するので、側壁部材 5 5, 5 6 は、指 F に対して水平な力成分だけでなく下向き（垂直方向）の成分、つまり指 F を基台 5 2, 5 3 に押圧する力成分を与えることができ、指 F を基台 5 2, 5 3 上に抱きしめるようにして安定に固定することが可能となる。

図 1 8 は光源部 1 1 の正面図であり、L E D 1 1 a と L E D

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1 1 b を備えた発光素子からなる。

LED 1 1 a として、中心波長 8 3 0 n m、半値幅 4 0 n m
の L 3 9 8 9（浜松ホトニクス（株）製）を使用し、LED 1
1 b として中心波長 8 9 0 n m、半値幅 5 0 n m の L 2 6 5 6
5（同上製）を使用している。なお、後述するように、「血管幅
計測モード」では LED 1 1 a のみを点灯させる。

このような構成において実施される血管幅および血液成分濃
度の計測手順を図 1 2 および図 1 3 に示すフローチャートを用
いて説明する。

10 （１）血管幅計測モード

まず、被検者が図 1，図 8 に示すように指 F を検出部 1 に挿
入すると、操作者は入力部 3 5 を操作して「血管幅計測モー
ド」を設定し（ステップ S 1）、LED 1 1 a（第 1 波長）に
よって指 F を照明して撮像する。それによって、図 1 4 に示す
15 ように、指 F の輪郭 1 6 a と共に、撮像部 1 2 側の皮膚近傍に
局在する血管（静脈）像 4 0 を含む組織の画像 4 1 が得られ出
力部 2 4 にモニター画像として出力される（ステップ S 2）。
次に、画像 4 1 において解析領域 R 1 が設定される（ステップ
S 3）。

20 解析領域 R 1 の設定手順は図 1 3 に示す手順により実行され
る。つまり、計測が第 1 回目であるときには（ステップ S 3
1）、解析領域設定部 3 4 が血管像 4 0 の最もコントラストの
よい領域を検索し、検索の結果、決定した領域を長形状の解
析領域 R 1 として設定する（ステップ S 3 2）。なお、解析領

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域 R 1 は通常、解析領域設定部 3 4 により自動的に設定されるが、使用者が出力部 2 4 に出力されるモニタ像を見ながら入力部 3 5 を操作して手動設定してもよい。

5 設定された解析領域 R 1 は、画像 4 1 の画面を X - Y 座標平面として、その各頂点の座標が記憶部 3 2 に記憶される（ステップ S 3 3）。次に、特徴抽出部 3 1 が、画像 4 1 の輪郭 1 6 a における関節部分のくぼみ位置 P 1 を抽出し、抽出した位置 P 1 の座標を記憶部 3 2 に格納する（ステップ S 3 4, S 3 5）。

10 また、ステップ 3 1 において、計測が第 2 回目以降である場合には、前のステップにおいて、例えば、図 1 5 に示すような画像 4 1 a が得られると、記憶されている解析領域 R 1 の座標が読み出されると共に、画像 4 1 a から関節部分のくぼみの位置 P 2 が特徴抽出部 3 1 によって抽出される（ステップ S 3 6, 15 S 3 7）。

次に、第 1 回の計測時に設定した位置 P 1 と今回抽出した位置 P 2 について座標の差 ΔX , ΔY が比較部 3 3 によって算出される（ステップ S 3 8）。そして、 ΔX , ΔY がいずれも所定の許容範囲 δ を越えない場合には（ステップ S 3 9）、解析 20 領域設定部 3 4 は初期に設定した解析領域 R 1 を ΔX , ΔY だけずらすことにより、新しい解析領域 R 2 を設定する（ステップ S 4 0）。

これによって領域 R 2 内の血管部位は、第 1 回目の計測時に設定された領域 R 1 内の血管部位と実質的に同一となる。この

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ようにして、一人の被検者の指について経時的（例えば、2時間おき）に n 回計測しても、解析領域 $R_1, R_2 \dots R_n$ がその都度設定され、常に血管の同一部位についての計測が行われる。なお、ステップS39において、 $\Delta X, \Delta Y$ のいずれかが許容値 δ を越えると、指16が検出部1に対して正常に設置されていないものと判断され、出力部24に「エラー」が表示される。

次に、図12のステップS4において、プロファイル抽出部21が、設定された解析領域 R_1 内で血管に垂直な方向の濃度プロファイル（図16）を作成する。そして、定量化部22は、この濃度プロファイルをベースラインで規格化する。ベースラインは、濃度プロファイルの血管部分以外の部分から、最小二乗法などによって求め、これで図16のプロファイルを図17に示すように規格化する（ステップS5）。このようにすることによって、入射光量に依存しない濃度プロファイルを得ることができる。

演算部23は、この規格化した濃度プロファイル（図17）からピーク高さ h_1 を求め、 $(1/2)h_1$ における分布幅（半値幅） w_1 を血管幅として算出し、記憶部25に格納する（ステップS6）。そして、所定回数の計測が完了すると、算出した血管幅からその経時変化を表わすグラフや表を作成して表示する（ステップS7～S9）。

図19は、1人の被検者の指について、2時間おきに計測し、血管幅 w_1 の相対的な経時変化をグラフにして出力部24に表

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示させた例である。

(2) 血液成分濃度計測モード

まず、操作者は、入力部 35 (図 1) を操作して図 12 に示すように「血液成分濃度計測モード」を設定し (ステップ S 1 5 1)、LED 11a (第 1 波長) と LED 11b (第 2 波長) とによって順に被検者の指 F を照明し、それぞれ撮像を行い (ステップ S 1 2, S 1 3)、第 1 波長により得られた画像について、ステップ S 3 と同じ手順、つまり図 13 に示す手順により解析領域を設定する (ステップ S 1 4)。

10 次に、プロファイル抽出部 21 が、第 1 および第 2 波長により得られた各画像について、それぞれの濃度プロファイル (図 16) を作成する (ステップ S 1 5)。定量化部 22 は、各濃度プロファイルをベースラインで図 17 に示すように規格化する (ステップ S 1 6)。

15 そこで、演算部 23 は、規格化された各濃度プロファイルについて、ピーク高さ h_1 , h_2 および半値幅 w_1 を算出し (ステップ S 1 7)、次のようにしてヘモグロビン濃度 HGB およびヘマトクリット HCT を算出する (ステップ S 1 8)。

つまり、第 1 波長における血液の散乱係数を S_1 、吸収係数
20 を A_1 とし、近似的に Beer の法則が成立しているとする
$$\log(1 - h_1) = -k(S_1 + A_1)w_1 \dots\dots (1)$$

である。ここで、 k は比例定数である。

ところで散乱係数 S_1 と吸収係数 A_1 は、それぞれ血液のヘマトクリット HCT とヘモグロビン量に比例すると考えられる。

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$$S_1 = \sigma_1 \cdot HCT, A_1 = \sigma_2 \cdot HGB \quad \dots\dots (2)$$

故に、

$$\log(1 - h_1) = - (k \sigma_1 \cdot HCT + k \sigma_2 \cdot HGB) \cdot w_1 \quad \dots\dots (3)$$

5 となる。

そこで、LED11b（第2波長）による画像から求めたピーク高 h_2 についても同様に、

$$\begin{aligned} \log(1 - h_2) &= -k(S_2 + A_2) \cdot w_1 \\ &= - (k \sigma_3 \cdot HCT + k \sigma_4 \cdot HGB) \cdot w_1 \quad \dots\dots (4) \end{aligned}$$

10

となる。

$k, \sigma_1, \sigma_2, \sigma_3, \sigma_4$ は実験的に決定されるので、 h_1, h_2, w_1 によりHGB, HCTが求まる。

しかしながら、実際には血管から表皮までに存在する組織に
15 よって画像はボケるため、観察されるピーク値は組織がない場合に比べて小さくなる。よって、

$$\log(1 - h_1) = -k(S + A)w_1 + T \quad \dots\dots (5)$$

となる。

ここで、Sは血液の散乱係数、Aは血液の吸収係数、Tは生
20 体組織による影響を表す項である。

さて、このTは、得られる画像の中で血管像のコントラストが最大となる部分を解析領域に選択することによって、比較的一定となることを実験的に見いだした。従って、実験的に求めたTを用いても実用上は問題とはならない。

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算出されたHGBとHCTは記憶部25に格納される。このような計測が所定回数くり返されると、演算部23は、算出した値からその経時的変化を表わすグラフや表を作成して表示する（ステップS19，S20）。

- 5 図20は、1人の被検者の指について2日おきに計測し、HGBとHCTの経時変化をグラフにして出力部24に表示させた例である。

第2実施例

- 10 図21はこの発明の第2実施例の検出部101を示す斜視図である。この実施例は第1実施例の検出部1の構成を変形したものであり、その他の構成は第1実施例と同等である。

図22～図27は、それぞれ検出部101を示す左側面図，平面図，正面図，背面図，底面図，縦断面図である。なお、右側面図は左側面図と対称であるので、ここでは図示しない。

- 15 図28は検出部101の要部切欠き側面図、図29は図28のW-W矢視断面図、図30と図31は要部の動作を示す説明図である。

- 20 この実施例では、手全体（手の平及び指）を無理なく自然な状態で安定して載置し測定することができ、載置時に被検者が疲れを感じることをないように工夫されている。

つまり、第1実施例の図3に示す基台部材51及びハウジング58を図21に示すように一つにまとめて中空の卵形状のハウジング151となし、ハウジング151の上面の頂上部分を第1実施例の基台52，53として機能させている。

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測定時には第 1 実施例の図 8 と同様に、中指 F を 2 つの側壁部材 1 5 5 と 1 5 6 の間に挿入すると共に、他の指を側壁部材 1 5 5 と 1 5 6 の外側に対照的に 2 本ずつ配置し、アーム 1 5 7 で中指 F を押圧するようにする（図 3 0，図 3 1 参照）。この時、ハウジング 1 5 1 上に手の平全体を載置することにより、その卵形の凸曲面が自然な状態における手の平とその指によって形成される凹曲面によく合致する。

図 2 9 に示すようにハウジング 1 5 1 は上部ハウジング 1 5 1 a と底部 1 5 1 b からなり、両者は周縁部を互いに嵌合することにより一体に接合されている。側壁部材 1 5 5，1 5 6 の下部は、ハウジング 1 5 1 の内部において上部ハウジング 1 5 1 a の内側から下方へ突出する突出部 1 5 4 a，1 5 4 b にそれぞれシャフト 1 6 5，1 6 6 により軸支され、スプリング 1 6 7，1 6 8 によってそれぞれ矢印 U，V 方向に付勢される。つまり、突出部 1 5 4 a，1 5 4 b とシャフト 1 6 5，1 6 6 は側壁部材 1 5 5，1 5 6 を矢印 U，V 方向に回転可能に支持するヒンジ機構を構成している。側壁部材 1 5 5，1 5 6 の上部はハウジング 1 5 1 の上部中央部に設けられた開口部 1 6 9 から外部に突出している。

20 生体の一部である指 F は 2 つの側壁部材 1 5 5，1 5 6 の間に設置され、両側から弾性的に挟持される（図 3 1）。ここでは測定対象の指 F を中指としているが、他の指でも測定可能である。

この実施例では中指 F を側壁部材 1 5 5，1 5 6 間に設置し

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各側壁部材 1 5 5, 1 5 6 の外側に他の指を 2 本ずつ載置するために、ハウジング 1 5 1 の表面に人指指, 薬指などを好適に載置できるよう各指形状に合致した窪み 1 8 1, 1 8 2, 1 8 3 (図 2 3, 図 3 1) を設けて、各指がハウジング 1 5 1 の表面によくフィットするようにしている。

また、側壁部材 1 5 5, 1 5 6 の外側壁部は、ハウジング 1 5 1 表面近傍においてくびれた凹部 1 5 5 a, 1 5 6 a を有し (図 2 4)、凹部 1 5 5 a, 1 5 6 a は中指の両側の指である人指指と薬指との各中指側曲面によくフィットする曲面を形成している。また、指載置部分において側壁部材 1 5 5, 1 5 6 の厚みが薄くなっているため、指を大きく広げることなく、自然な状態で手の平と指を載置して測定を行うことができる。

さらにフィット感を高めるため、例えば図 3 0 と図 3 1 に示すように側壁部材 1 5 5, 1 5 6 の内側壁部に工夫をしてもよい。図 3 0 と図 3 1 は側壁部材 1 5 5, 1 5 6 をそれぞれ上方と正面から見た図である。この場合、側壁部材 1 5 5, 1 5 6 の内側壁部にはゴムやスポンジ等の不透光性の軟質の弾性体 1 5 5 b, 1 5 6 b が設けられている (黒色が好ましい)。このため側壁部材 1 5 5, 1 5 6 は中指 F をその形状に合わせて無理なく安定して挟持することができる。

また、光源部 1 1 1 (図 2 7) から照射された光が側壁部材 1 5 5, 1 5 6 と指 F の間に生じた隙間から撮像部 1 2 側へ漏れるということがなくなるので、より良好な光情報を得ることができるという効果も生じる。

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図 2 7 に示すように、アーム 1 5 7 は一端部においてハウジング 1 5 1 内で上部ハウジング 1 5 1 a の内面から下方へ突出する突出部 1 5 9 にシャフト 1 6 2 により回動可能に支持され、開口 1 9 0 から突出している。

- 5 アーム 1 5 7 は、他端部が図 2 7 に示すように側壁部材 1 5 5, 1 5 6 に近い位置にあるときは側壁部材 1 5 5, 1 5 6 に近づく方向つまり矢印 T 1 方向に回転しようとし、図 2 8 に示すように側壁部材 1 5 5, 1 5 6 から遠い位置にあるときには側壁部材 1 5 5, 1 5 6 から遠ざかる方向つまり矢印 T 2 方向
- 10 に回転しようとするようなトグル機構により支持されている。

- このトグル機構では、図 2 7 に示すようにアーム 1 5 7 の端部と突出部 1 5 9 にはそれぞれ突起 1 6 1 と 1 6 3 が設けられ、その間にスプリング 1 6 0 が掛け渡されている。アーム 1 5 7 の矢印 T 1 又は T 2 方向への回転により突起 1 6 1, 1 6 3 間の距離が変化する。アーム 1 5 7 が図 2 7 のように側壁部材 1 5 5, 1 5 6 に当接している状態を初期位置とし、アーム 1 5 7 を矢印 T 2 方向に回転させていくと突起間 1 6 1, 1 6 3 の距離が増大するのでスプリング 1 6 0 は突起間距離を縮めようとする。すなわちアーム 1 5 7 は側壁部材 1 5 5, 1 5 6 側へ
- 15 戻ろうとする。
- 20 戻ろうとする。

アーム 1 5 7 をさらに矢印 T 2 方向に回転させ、突起 1 6 1, シャフト 1 6 2, 突起 1 6 3 が一直線状になる状態を境にして突起間距離が減少するのでアーム 1 5 7 は逆に側壁部材 1 5 5, 1 5 6 から遠ざかる方向に回転しようとする。そして、アーム

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1 5 7 の背がハウジング開口 1 9 0 の縁に当接した状態で回転を停止する。このことにより、被験者は、一方の手の中指を側壁部材 1 5 5, 1 5 6 間に挿入するとき、他方の手でアーム 1 5 7 を開いて保持しておく必要がなくなるので操作性が向上する。

この実施例では、図 2 7 に示すように、第 1 実施例の光源部 1 1 と同様に、アーム 1 5 7 の他端部には指 F に光照射するための光源部 1 1 1 が設けられ、ハウジング 1 5 1 の内部には第 1 実施例の撮像部 1 2 と同等の撮像部 1 2 が設けられ、さらに、
10 ハウジング 1 5 1 の開口部 1 6 9 には、第 1 実施例のガラス板 7 0 に対応するアクリル樹脂製の光透過板 1 7 0 が設けられている。なお、1 7 1 は光透光板 1 7 0 と撮像部 1 2 を接続するフードである。

光源部 1 1 1 では、基板 1 5 7 a 上に実施例 1 の光源部に用いた図 1 8 に示す発光素子 1 1 を 2 個載置して光量の増大を計り、発光素子 1 1 が下向きになるようにアーム 1 5 7 の他端部の開口部 1 5 7 a の上部に基板 1 5 7 d を設置している。さらに、開口部 1 5 7 a は下向きに末広がりの壁面 1 5 7 d を有し、その壁面には、白色又は銀色塗装が施され、2 つの発光素子 1
20 1 からの光が撮像部 1 2 の方向へ効率よく反射されるようになっている。

また、指 F に光を照射する場合、皮膚表面の微細な凹凸により光が乱反射して、生体内部に十分な光を供給することができないことがある。そこで、この実施例では指 F の内部への光の

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入射効率を高めるため、光出射部分に指 F と接触する透光性部材 1 5 7 c を開口部 1 5 7 a に配置し、皮膚表面の凹凸をなくした上で光照射するようにしている。これによって、指 F の内部に効率よく光が供給されるので撮像部 1 2 で良好な光情報を
5 得ることができる。なお、透光性部材 1 5 7 c は図 2 7 のように、下向きに凸、つまり指 F 側に凸の形状を有すると効果的である。

また、アーム 1 5 7 は図 2 7 に示すように中空状に設計され、アーム 1 5 7 内にリード線 2 0 0 が設けられ、光源部 1 1 1 への電力の供給は、解析部（パーソナルコンピュータ）2（図
10 2）からケーブル 3，基板 2 0 1，コネクタ 2 0 2 およびリード線 2 0 0 を介して行われるようになっているので、コネクタ 2 0 2 においてリード線 2 0 0 は基板 2 0 1 から分離できる。このような構成により、この実施例の検出部 1 0 1 は、
15 上部ハウジング 1 5 1 a 側と下部ハウジング 1 5 1 b 側とに分離できるので、製造時の組立てやメンテナンス時の内部チェックが容易になる。

図 2 3 に示すように、側壁部材 1 5 5，1 5 6 の上面には、それぞれ位置決めマーク 2 0 3，2 0 4 が設けられている。これらは、測定時に指 F を側壁部材 1 5 5，1 5 6 間に挿入するとき、指 F の長手方向の位置決めを行うためのものであり、例えば、指 F の第 2 関節をこのマークに一致させる。
20

また、図 2 6 に示すように下部ハウジング 1 5 1 の底面には、4 つのすべり止めのゴム座 2 0 5 と、電源用スライドスイッチ

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206の操作片が突出しているが、ゴム座205の高さはその操作片よりも高く設計されている。

なお、スライドスイッチ206は、光源部111および撮像部12に供給する電力をオン・オフするものであり、これを上部ハウジング151に設置すると、被験者が手をハウジング151上に載置する時にその操作片が障害になるので、この位置に設けられている。

第3実施例

図32はこの発明の検出部と解析部の第3実施例の構成を示すブロック図である。同図において、解析部2aは、第1実施例の解析部2（図1）に判定部26と光量制御部27とを追加したものであり、その他において図1と同じ要素には同じ番号を付している。

第1および第2実施例のように生体の一部としてヒトの手の指（中指）を検出対象とする場合には、その関節部分において血管が皮膚の表面近傍に存在して撮像が容易であることから、解析領域R1（図14）が関節部分又はその近傍に設定されることが好ましい。

そのため、この実施例では第1又は第2実施例の計測作業（図12）を行う前に、予備工程を行うようにしている。つまり、被験者が検出部1に指Fを載置するときその関節部分が撮像部12の撮像領域に対して適正な位置にあるか否かを判定部26が判定し、適正な位置にない場合にはその旨を出力部24に出力して被験者に伝達し、指を正しく載置するよう促すよう

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にしている。

さらに、この予備工程では、光量制御部 2 7 が光源部 1 1 又は 1 1 1 の光量を撮像部 1 2 から得られる画像情報に基づいて適正にフィードバック制御し、光量調整を行うようにしている。

5 次に、判定部 2 6 および光量制御部 2 7 の動作について図 3 3 に示すフローチャートを用いて詳述する。

図 1 2 に示す計測の開始時に被験者が指を検出部 1 に載置したとき、まず、操作者は入力部 3 5 を操作して光源部 1 1 又は 1 1 1 によってその指を照明して撮像を行うと、図 3 4 に示す
10 ように a (640 画素) \times b (480 画素) の画面に輪郭 1 6 a を有する指の画像が得られる。そこで、判定部 2 6 は、予め画像領域の中央部に設定した判定領域 S (c (352 画素) \times d (240 画素)) 内の全画素の平均輝度 Q と基準値 Q_0 との差が所定値 δ , より大きいかな否かを判定する (ステップ S 5
15 3) 。 Q と Q_0 との差が δ , 以上の場合には、その差が δ , より小さくなるまで LED 1 1 a 又は 1 1 b へ供給する駆動電流を光量制御部 2 7 が制御して光量の粗調整を行う (ステップ S 5 7, S 5 2, S 5 3) 。

ところで、被験者が指を検出部 1 に載置したときに、指がそ
20 の長手方向に対して直交する方向つまり左右方向に適正位置からずれると、側壁部材 5 5, 5 6 又は 1 5 5, 1 5 6 と指との隙間から光源部 1 1 又は 1 1 1 の光の一部が漏れて、撮像部 1 2 から得られる画像内に図 3 5 に示すような高輝度の漏光像 K が現れ適正な画像分析の妨げとなる。

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そこで、判定部 26 は漏光像 K の存在の有無を次のようにして検出する（ステップ S 54）。

まず、図 36 に示すように Y 方向に延びる帯状の画素グループ（ 8×480 画素）を 1 グループとして粗分画し、各グループ毎に Y 方向の輝度のプロファイルを求める。図 37 は漏光像 K を横切る場合のプロファイル例であり、図 38 は漏光像 K を横切らない場合のプロファイル例である。判定部 26 は、求めた各グループのプロファイルからその立ち上がりおよび立ち下がり位置を検出しそれらを線で結び、図 39 に示すような外縁線 16b, 16c としてそれぞれ認識する。

次に同図に示すように外縁線 16b, 16c の内側にそれぞれ幅 ΔY 画素の内側領域を設定し、両方の内側領域の平均輝度 B_f を算出する。両方の内側領域において $B_f \times k$ （ k は 1 より大きい所定の定数）より高い輝度の画素が所定数より多いとき、漏光像 K が存在する、つまり光源部 11 又は 111 の光が漏れて撮像部 12 へ直接入射していると判定する（ステップ S 54）。

漏光像 K の検出時には判定部 26 は指の左右方向のずれが検出できるので、その検出結果に応じて「もっと右に配置して下さい」とか「もっと左に配置して下さい」又は「指を抜いて再度挿入して下さい」というメッセージを出力部 24 に出力させる（ステップ S 58）。

ステップ S 54 において漏光像 K が検出されない場合には、判定部 26 は関節部分が領域 S（図 34）内に存在するか否か

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を判定する（ステップ S 5 5）。図 4 0 に示すように関節部分 J は他の画像部分に比べて輝度が高いのでその位置は次のようにして容易に識別される。

つまり、判定部 2 6 は図 4 1 に示すように全画像領域（ $a \times b$ ）の中に長さ a 、幅 c （3 5 2 画素）からなる検索領域 S 1 を設定し、検索領域 S 1 内の 8×8 画素を 1 グループとして粗分画する。判定部 2 6 は、各グループの画素の平均輝度を算出し、その平均輝度が最大となるグループの位置を関節部分 J の位置として検出する。

10 また、判定部 2 6 は、検索領域 S 1 を図 4 2 に示すように Y 方向に延びる帯状の画素グループ（ $8 \times 3 5 2$ 画素）を 1 グループとして粗分画し、各グループの画素の平均輝度を算出し、その平均輝度が最大となるグループの位置を関節部分 J の位置（X 座標位置）として検出してもよい。

15 なお、光源部 1 1 又は 1 1 1 の照射特性などにより、判定部 2 6 が上記のようにして検索した関節部分 J の位置が、実際の関節部分の位置と若干ずれることがある。そのような場合には、判定部 2 6 は上記のように検索した関節部分 J の位置を適当な補正関数に代入して真の関節部分の位置を算出するようにして
20 もよい。

そして、判定部 2 6 は、関節部分 J が領域 S（図 3 4）の外にある場合には、「もっと奥に配置して下さい」とか「もっと手前に配置して下さい」というメッセージを出力部 2 4 に出力させる（ステップ S 5 9）。

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- また、ステップ S 5 5 において関節部分 J が領域 S 内にある場合には、判定部 2 6 はその関節部分 J の位置の X 座標がその中心になるように図 3 4 の領域 S を X 軸に平行に移動させ、移動させた領域 S 内の全画素の平均輝度 Q と基準値 Q_0 との差が
- 5 所定値 δ_2 より大きいか否かを判定する（ステップ S 5 6）。
- Q と Q_0 との差が δ_2 以上の場合には、その差が δ_2 より小さくなるまで LED 1 1 a 又は 1 1 b へ供給する駆動電流を光量制御部 2 7 が制御して光量の微調整を行う（ステップ S 6 0, S 6 1, S 5 6）。
- 10 このようにして、判定部 2 6 が指の載置状態と光源の光量について適正であると判定すると、第 1 又は第 2 実施例に示すように図 1 2 に示す計測作業が開始される。以下の作業は、第 1 又は第 2 実施例と同等であるので説明を省略する。

- なお、図 1 2 の計測作業において、ステップ S 2, S 1 2,
- 15 S 1 3 の前にそれぞれ図 3 3 に示す工程が挿入されるが、図 3 3 の工程が、ステップ S 2, S 1 2 の前に挿入される場合にはステップ S 5 2 における撮像は第 1 波長で、ステップ S 1 3 の前に挿入される場合には第 2 波長で行われる。

- また、出力部 2 4 にスピーカを設けステップ S 5 8, S 5 9
- 20 において、メッセージを音声で出力させてもよい。

産業上の利用可能性

この発明によれば、測定対象の生体の一部が無理なく安定して固定されるので、正確で再現性のよい検査結果が得られる。

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請求の範囲

1. 検査対象とする生体の一部を載置する基台と、載置された生体の一部を両側から挟持可能な側壁部材と、基台及び側壁部材により保持された生体に光を供給する光源部と、光をうけた生体の一部から光学的情報を検出する受光部とを備えてなる生体検査装置。
2. 各側壁部材は、互いに接近するように付勢されてなる請求項 1 記載の生体検査装置。
- 10 3. 基台は、両側側壁部材を互いに接近する方向に移動可能に支持する支持部材と、両側壁部材を互いに接近する方向に付勢する付勢部材とを備えてなる請求項 1 記載の生体検査装置。
4. 支持部材が、ヒンジ機構からなり、かつ付勢部材が、スプリングからなる請求項 3 記載の生体検査装置。
- 15 5. 側壁部材は、生体の一部を挟持する状態において、その生体の一部を基台方向に押圧する力成分が生じるように付勢される請求項 1 記載の生体検査装置。
6. 基台は、載置される生体の一部の形態にその表面の少なくとも一部が適合するように形成されてなる請求項 1 記載の生体
- 20 検査装置。
7. 光学的情報が、血管と血管を流れる血液の情報である請求項 1 記載の生体検査装置。
8. 検査対象とする生体の一部が、ヒトの手の指であり、かつ基台が、指と掌によって形成される曲面に適合可能な表面形状

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を有し、側壁部材は、その複数の指と掌が基台上に載置される
とき検査対象の指を両側から挟むように基台から突出してなる
請求項 1 記載の生体検査装置。

9. 基台は、その上面に指を位置決めするための少なくとも 1
5 つの窪みを備えてなる請求項 8 記載の生体検査装置。

10. 指が、中指である請求項 8 記載の生体検査装置。

11. 基台は、その上面に中指とその両側の指を位置決めする
ための複数の窪みを備えてなる請求項 10 記載の生体撮像装置。

12. カバー部材をさらに備え、そのカバー部材は、側壁部材
10 に挟持された生体の一部の上方を覆うことができる請求項 1 に
記載の生体検査装置。

13. 光源部が、カバー部材に設けられ、かつ受光部は、光源
から生体の一部を透過した光を基台に設けた開口を介して受光
するように基台の下方に設けられてなる請求項 12 記載の生体
15 検査装置。

14. 光源部が、LED からなり、かつ受光部が、CCD から
なる請求項 1 記載の生体検査装置。

15. 各側壁部材は、生体の一部に接触可能な弾性部材を備え
てなる請求項 1 記載の生体検査装置。

20 16. 透光性部材をさらに備え、その透光部材は、2つの側壁
部材に挟持された生体の一部に接触可能に設けられ、かつ光源
部は、その透光性部材を介して生体に光を供給する請求項 1 に
記載の生体検査装置。

17. 受光部が、撮像素子からなる請求項 1 ～ 16 のいずれか

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1 つに記載の生体検査装置。

18. 受光部が、撮像素子からなる請求項 1 ～ 16 のいずれか
1 つに記載の生体検査装置によって得られた血管を含む組織の
画像を解析してその血管を流れる血液に関する情報を算出する

5 解析部と、算出された情報を出力する出力部とを備えてなる非
侵襲血液分析装置。

19. 解析条件を入力する入力部をさらに備え、解析部は得ら
れた血管を含む組織の画像を入力された解析条件に基づいて解
析する請求項 18 記載の非侵襲血液分析装置。

10 20. 血液に関する情報が、ヘモグロビン濃度とヘマトクリッ
トの情報である請求項 18 記載の非侵襲血液分析装置。

21. 生体撮像装置により得られた画像に基づいて生体の一部
の基台に対する載置状態を判定する判定部と、判定部により判
定された載置状態に基づく指示メッセージを出力するメッセー
15 ジ出力部とをさらに備えてなる請求項 18 記載の非侵襲血液分
析装置。

22. 生体撮像装置により得られた画像情報に基づいて光源部
の光量を制御する光量制御部をさらに備えてなる請求項 18 記
載の非侵襲血液分析装置。

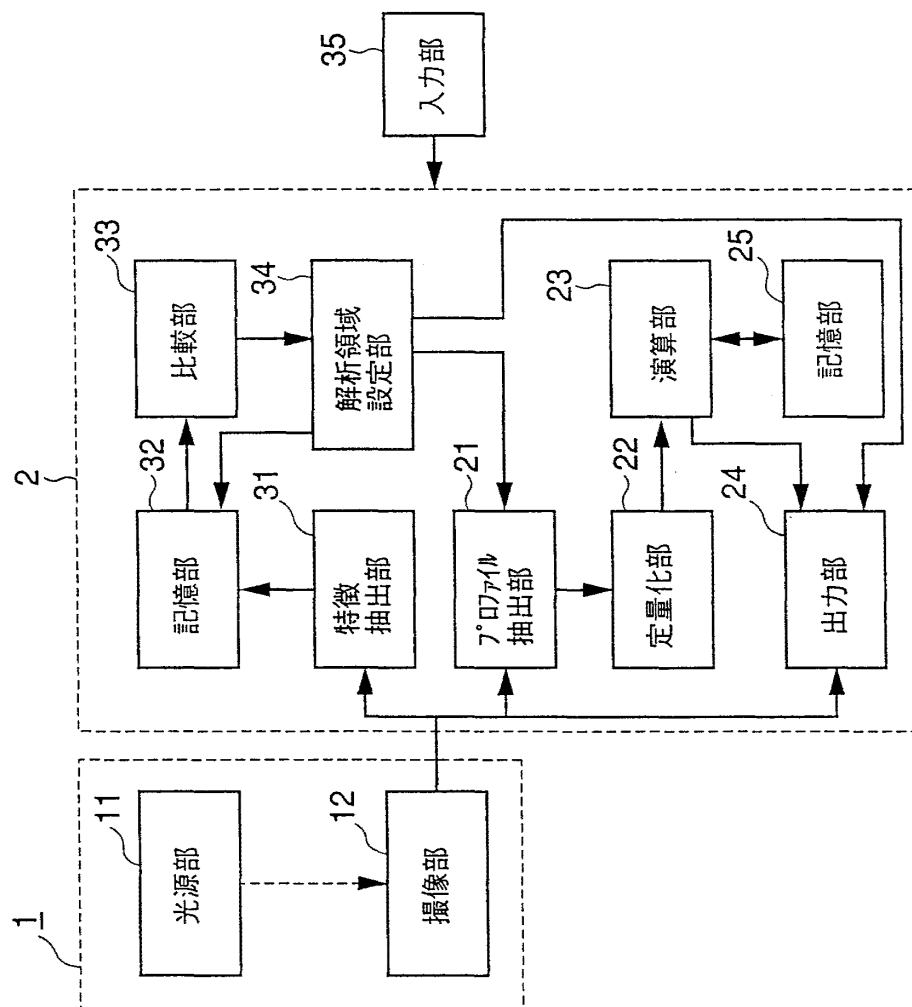
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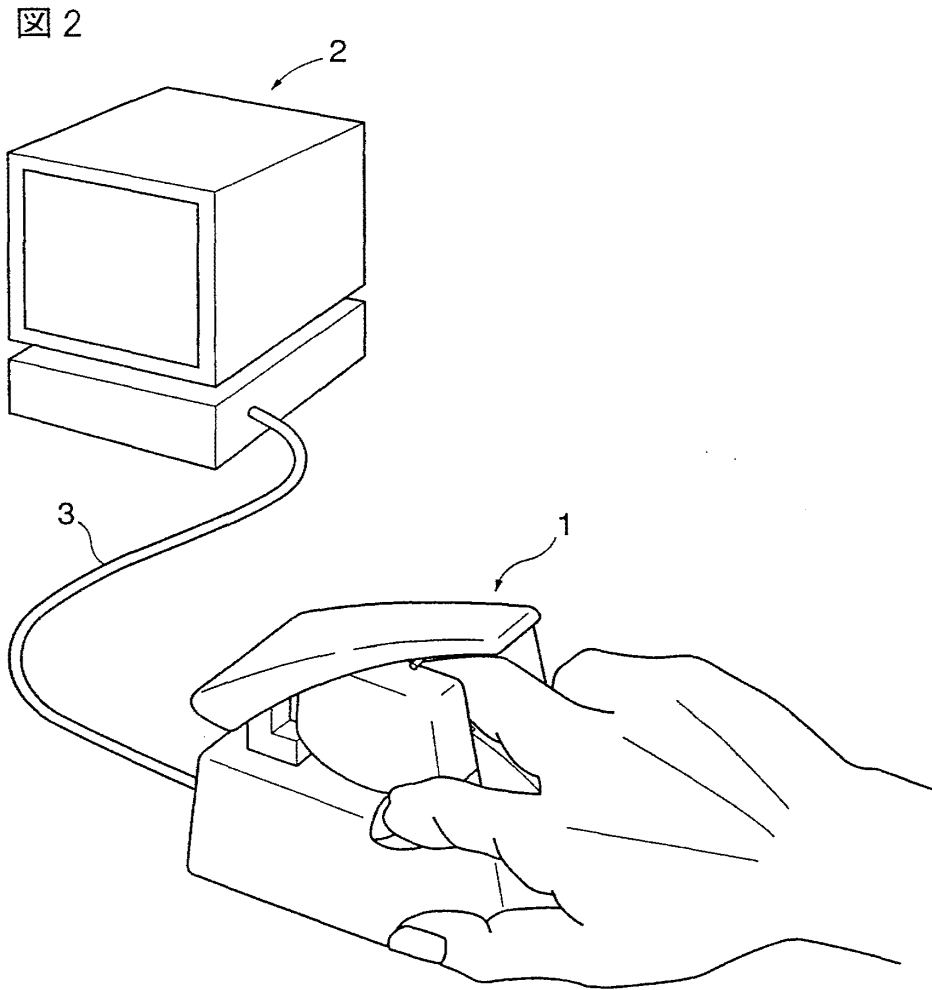
図1



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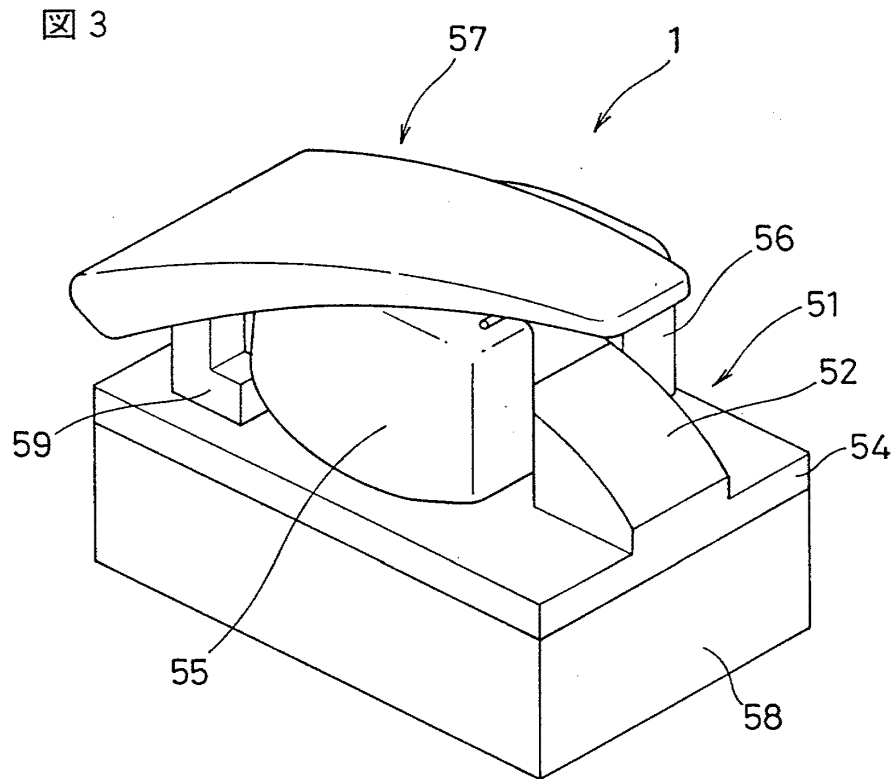
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3 / 3 0

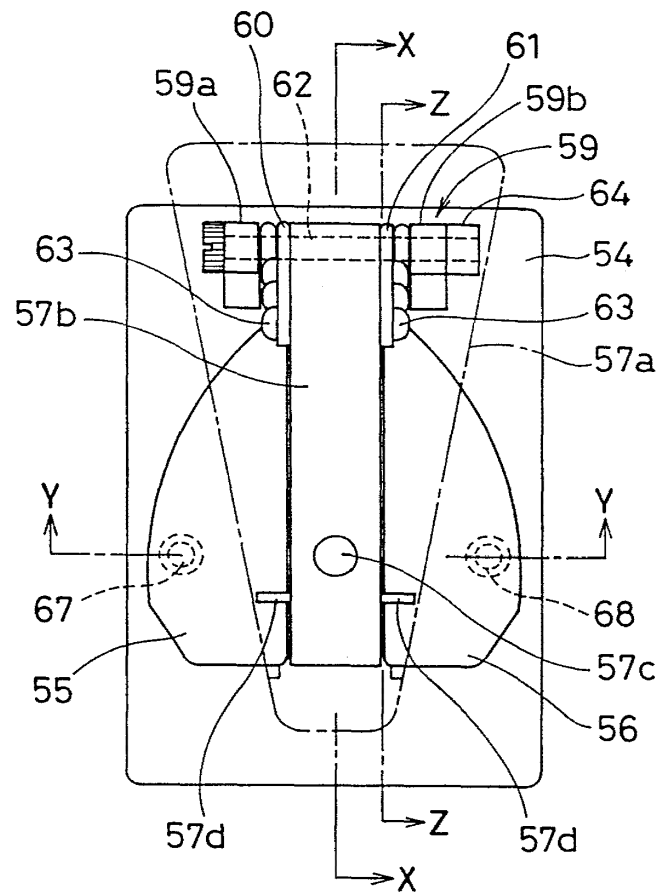


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図 4

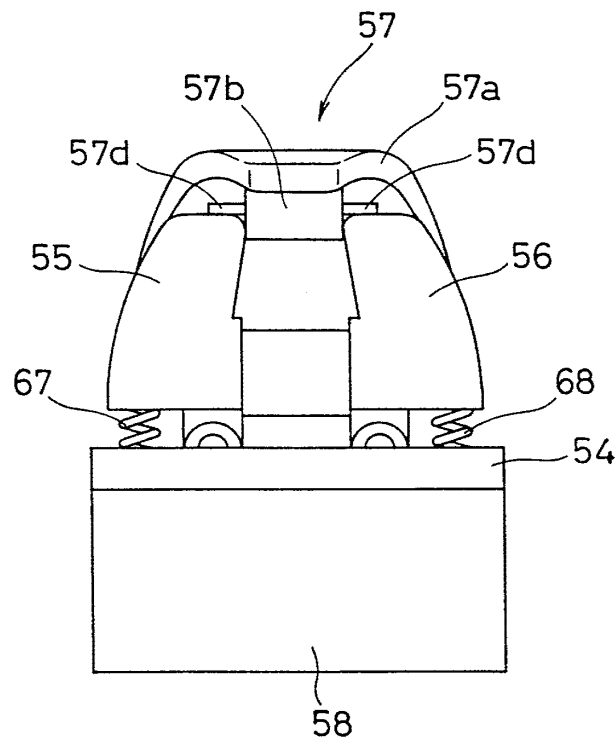


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図 5

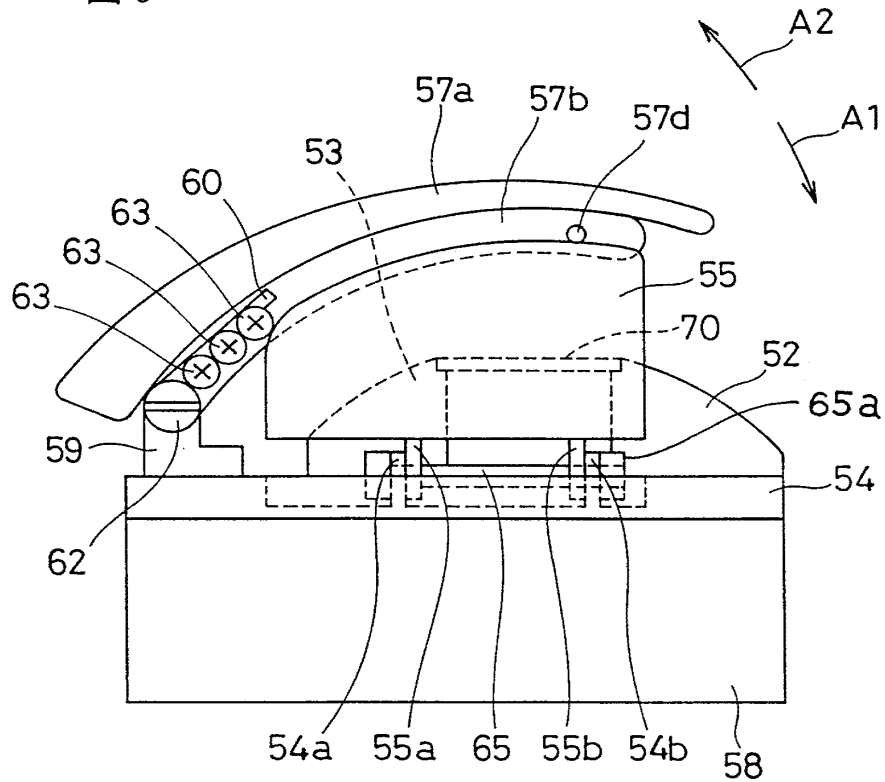


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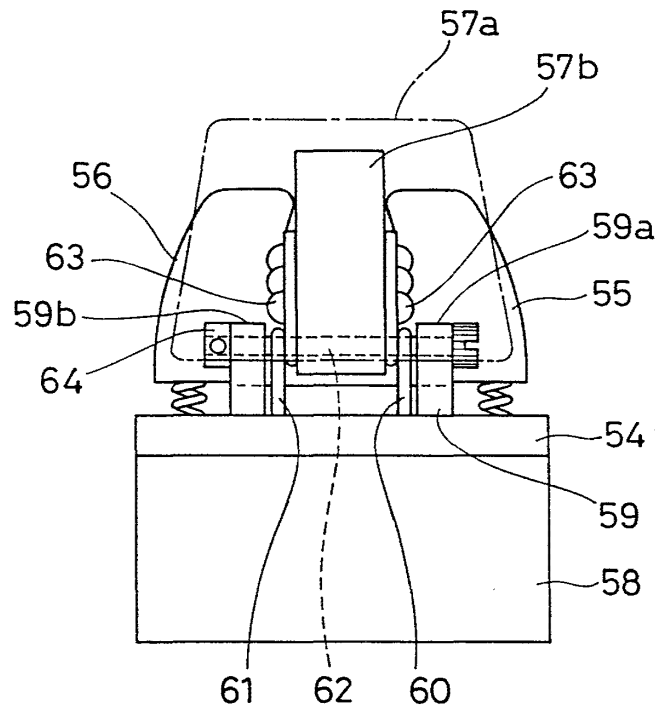


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図 7

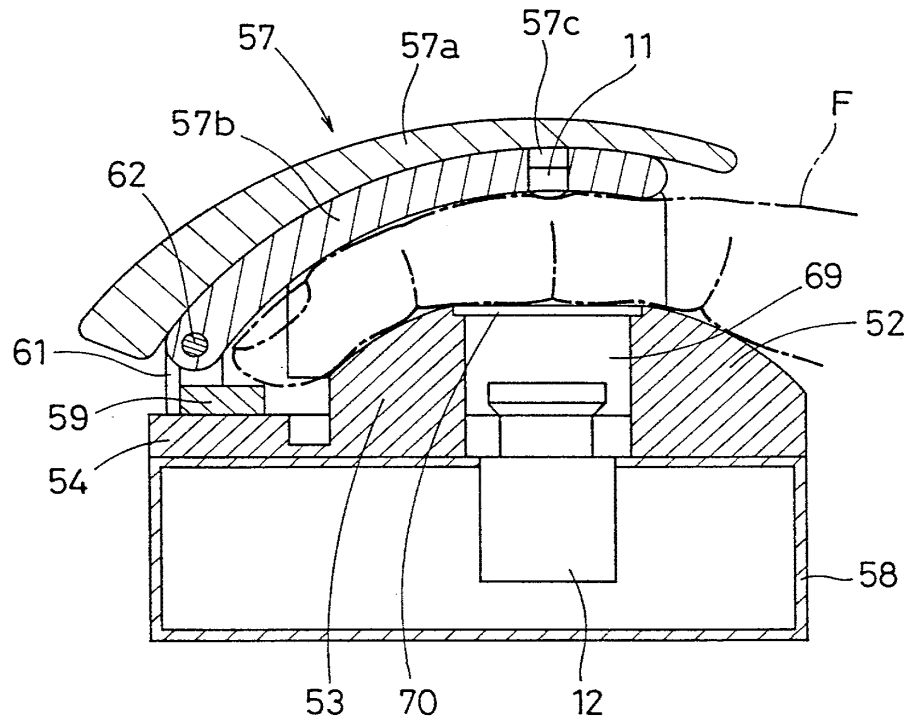


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8

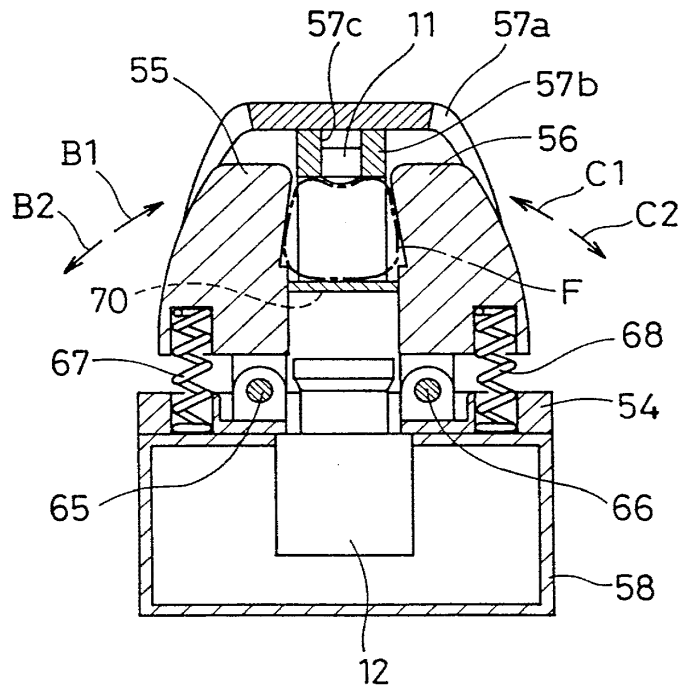


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図 9



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図 10

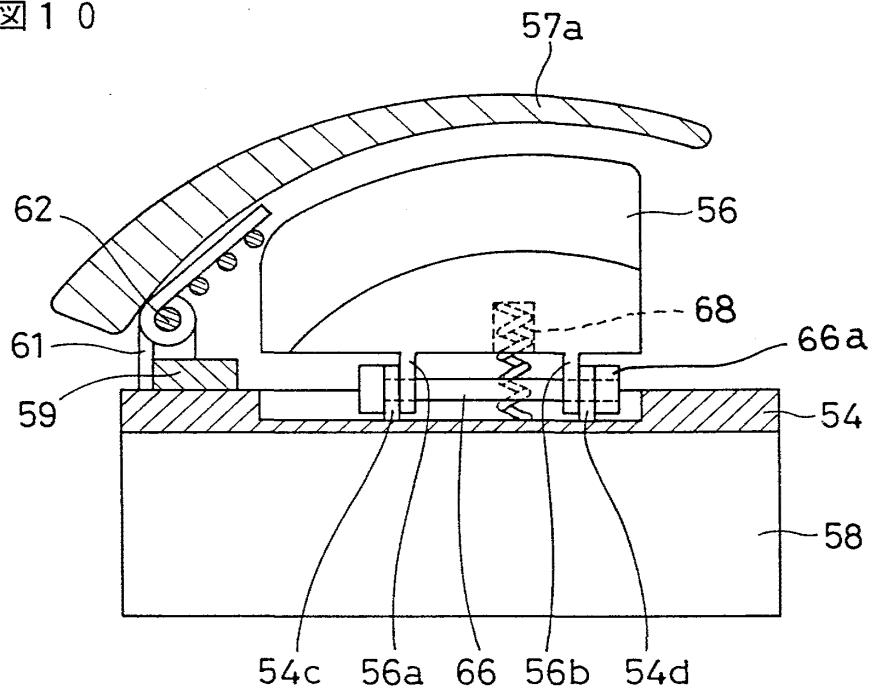
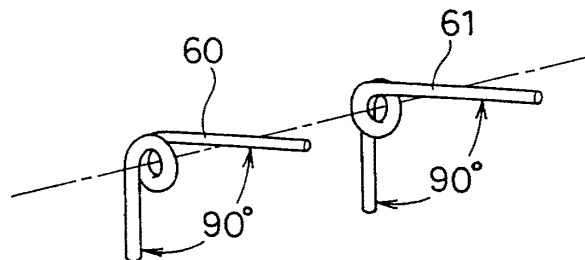


図 11

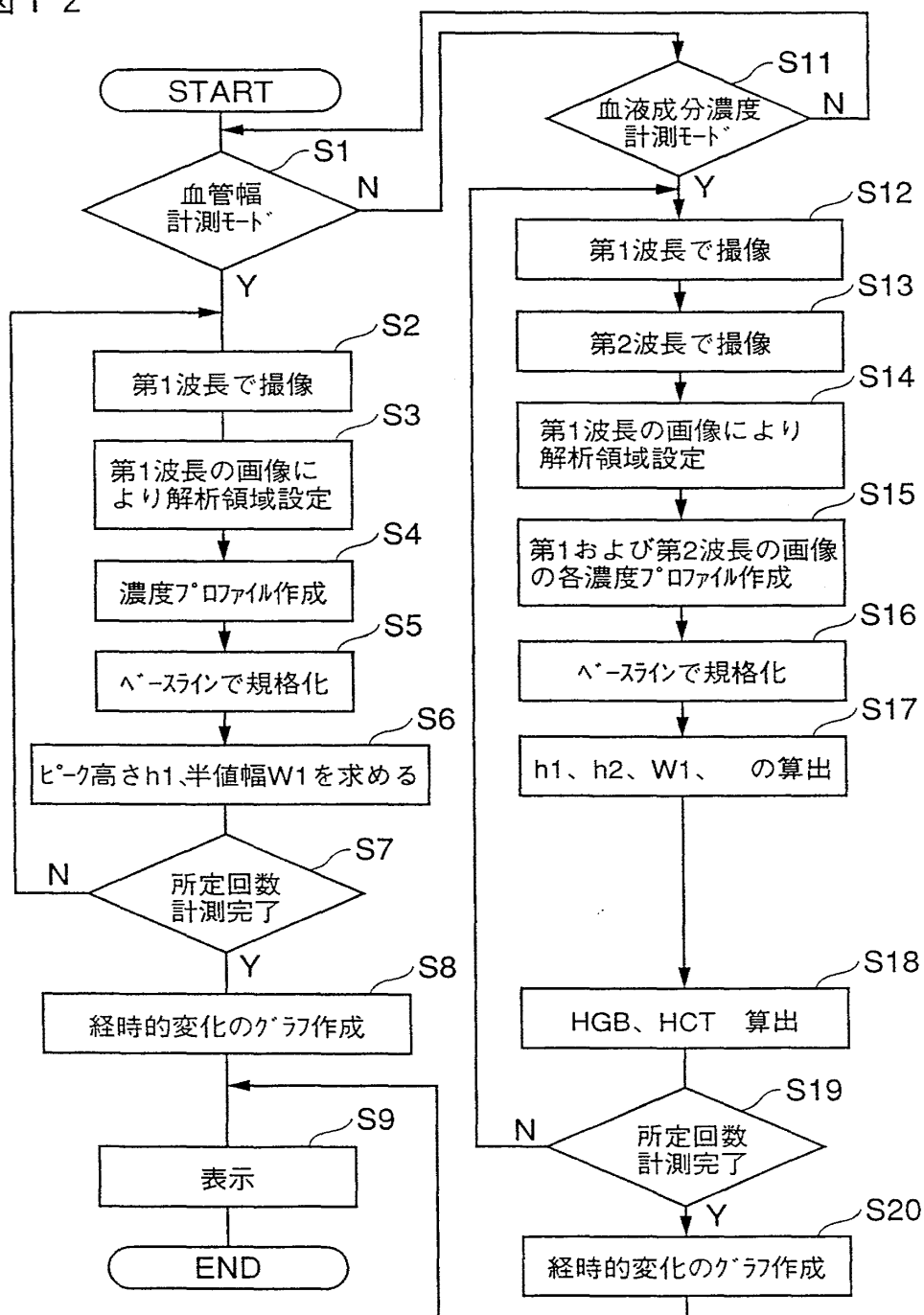


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図 12

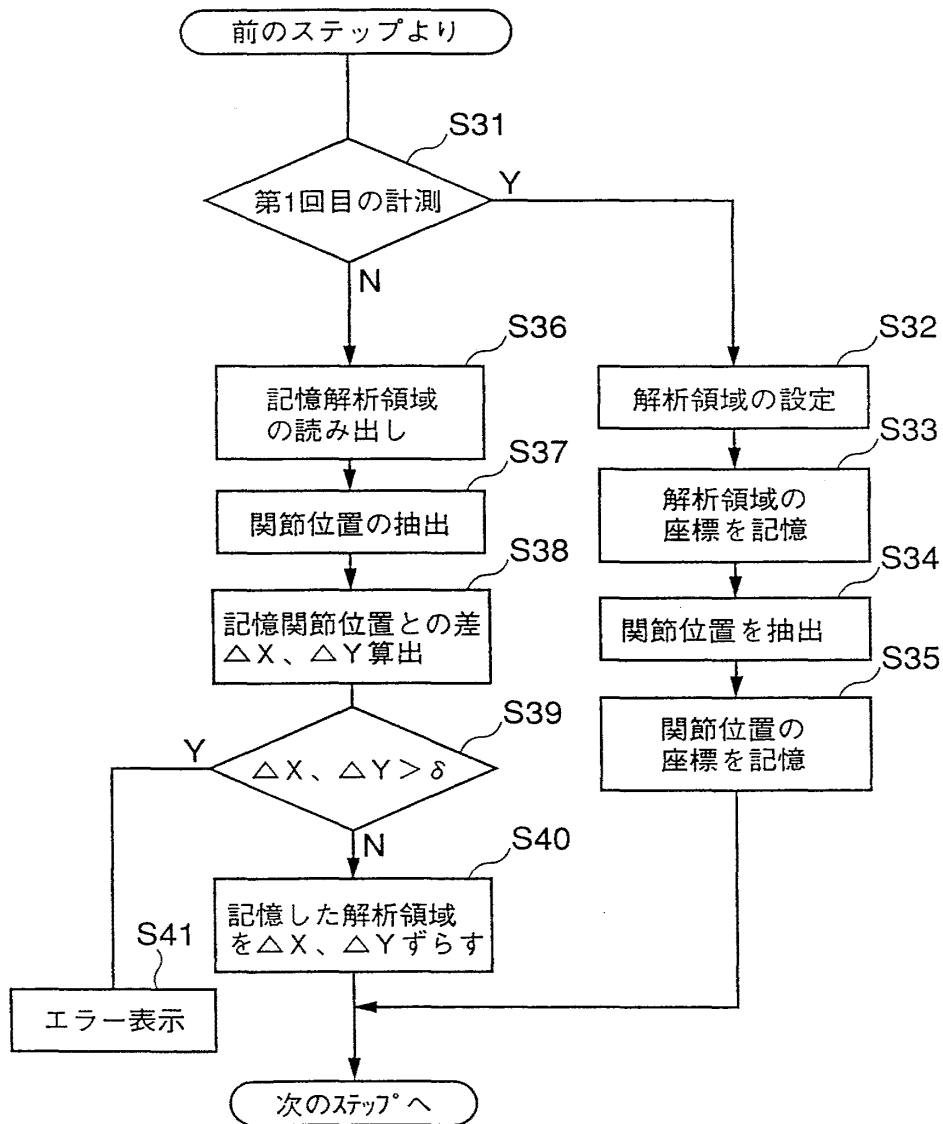


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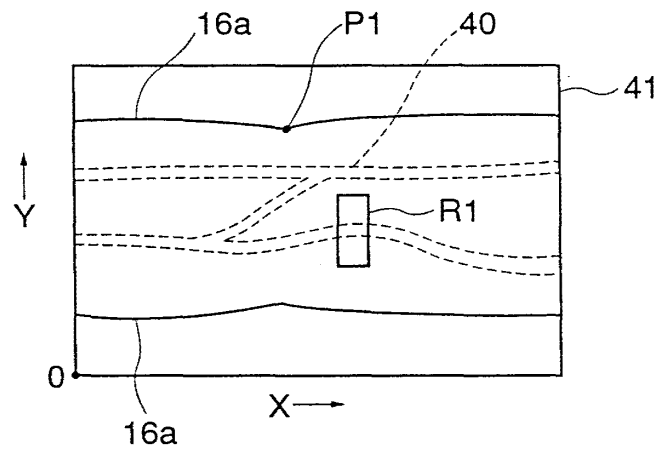
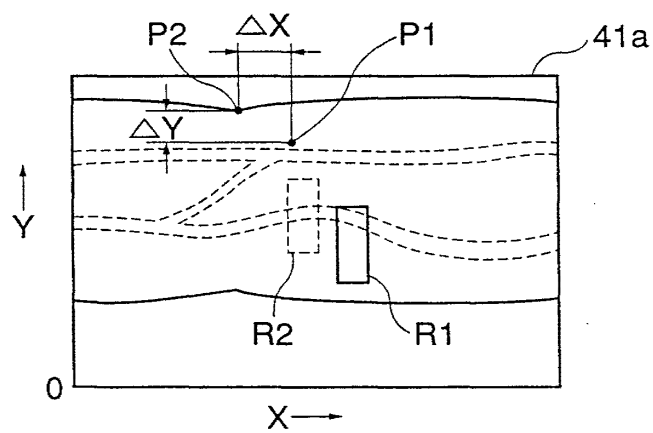


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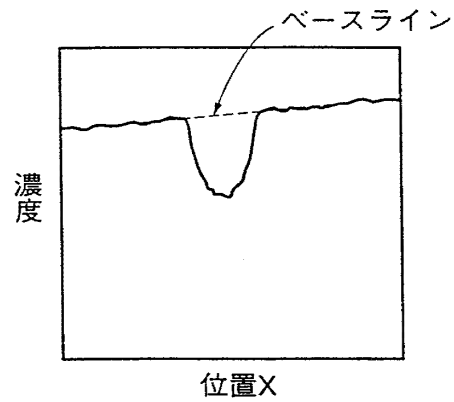
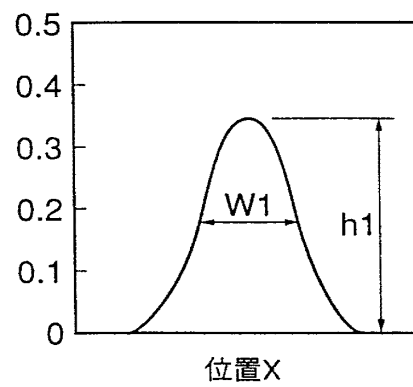


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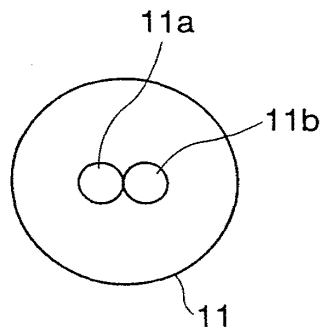
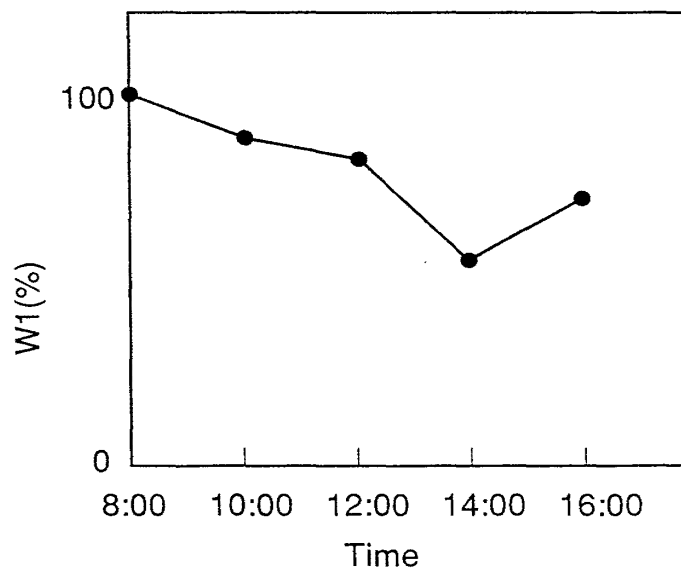


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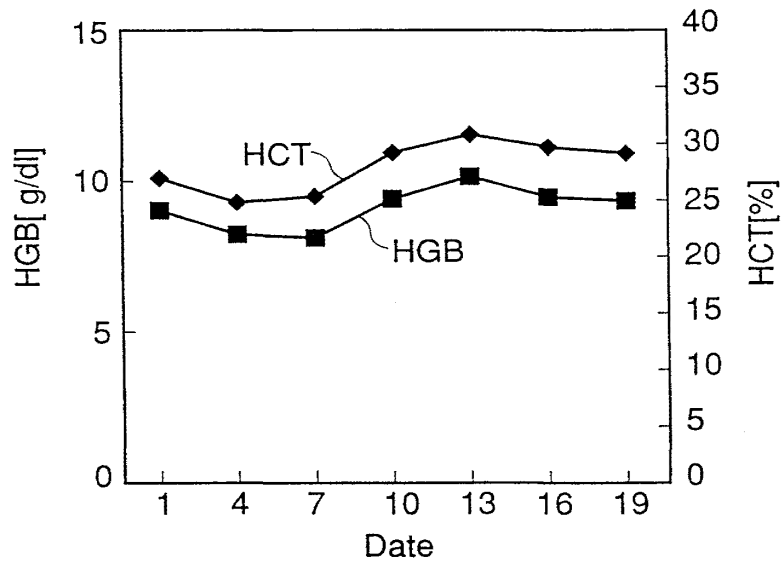
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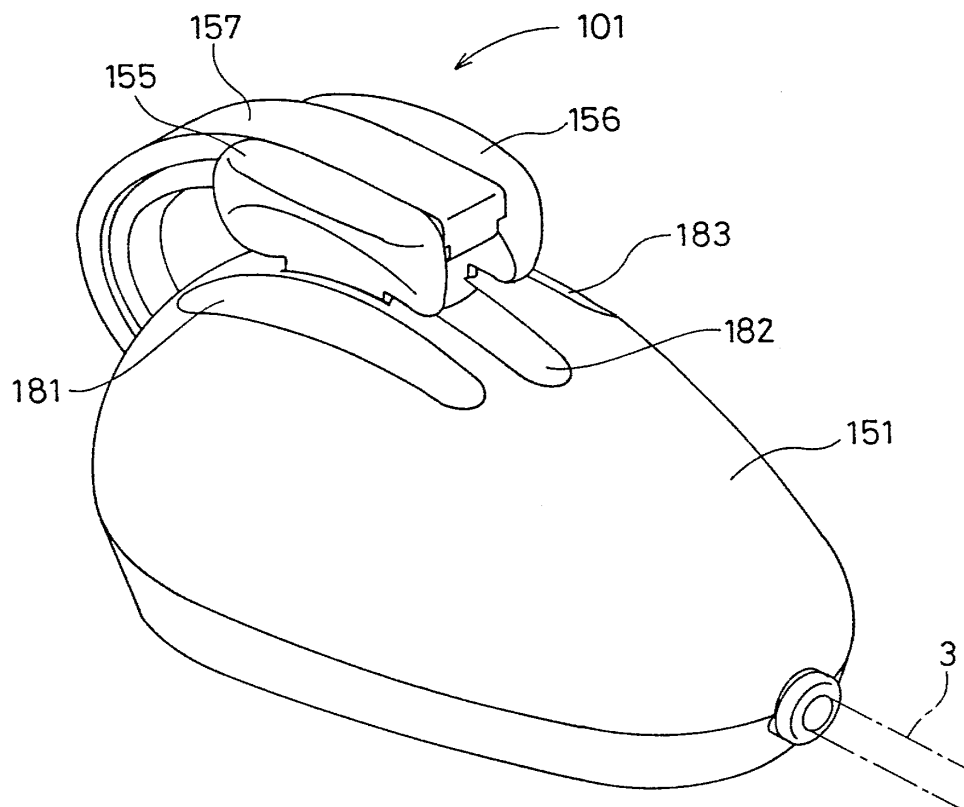


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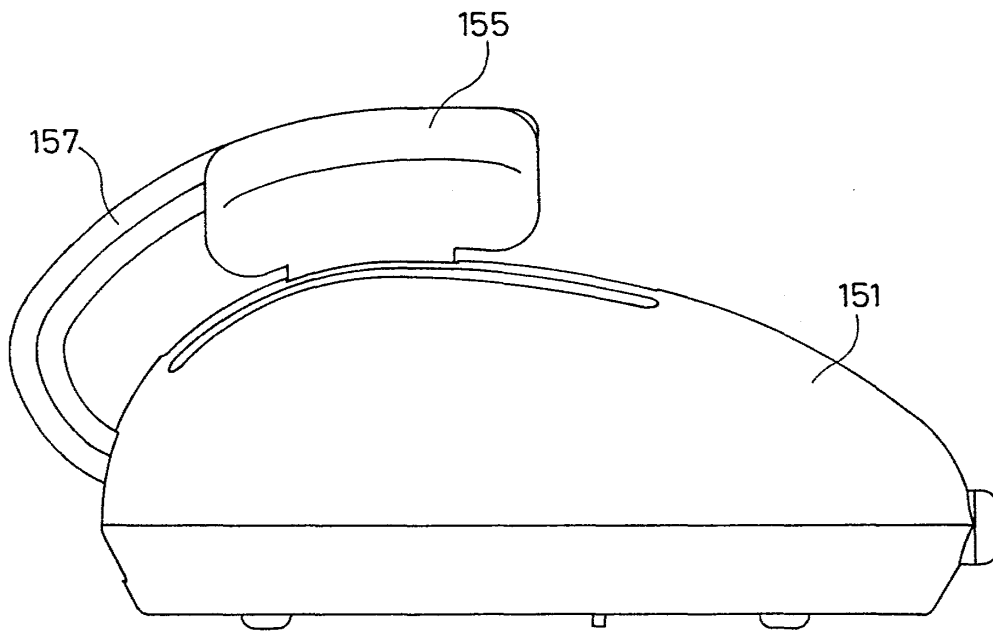
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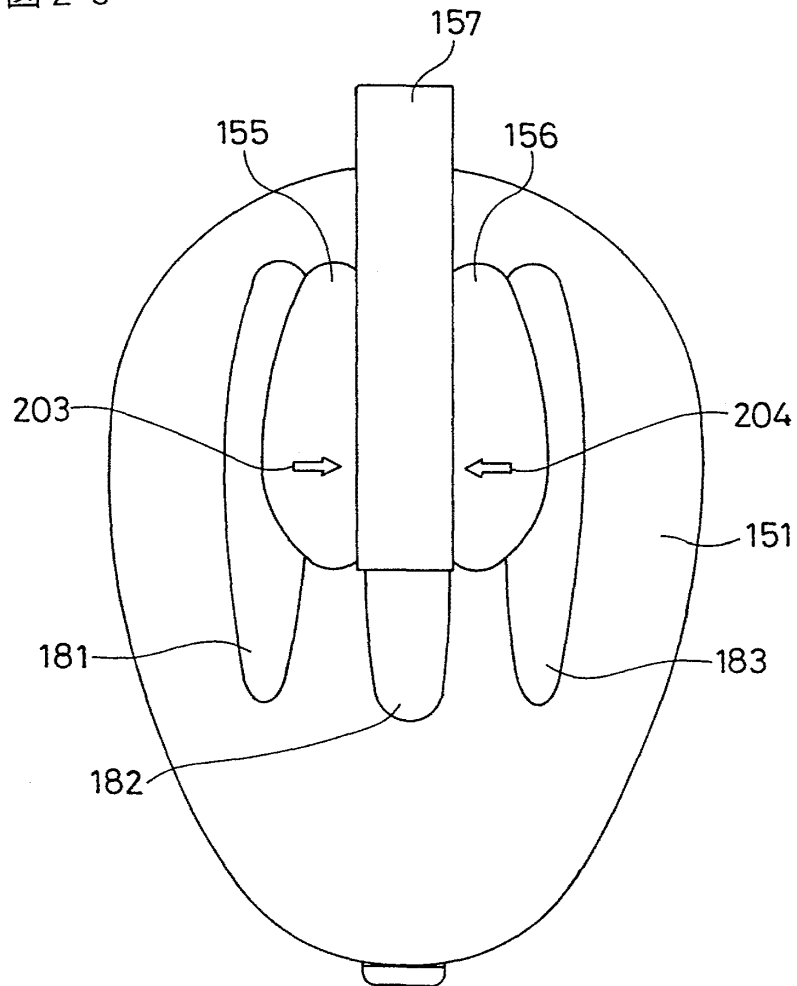


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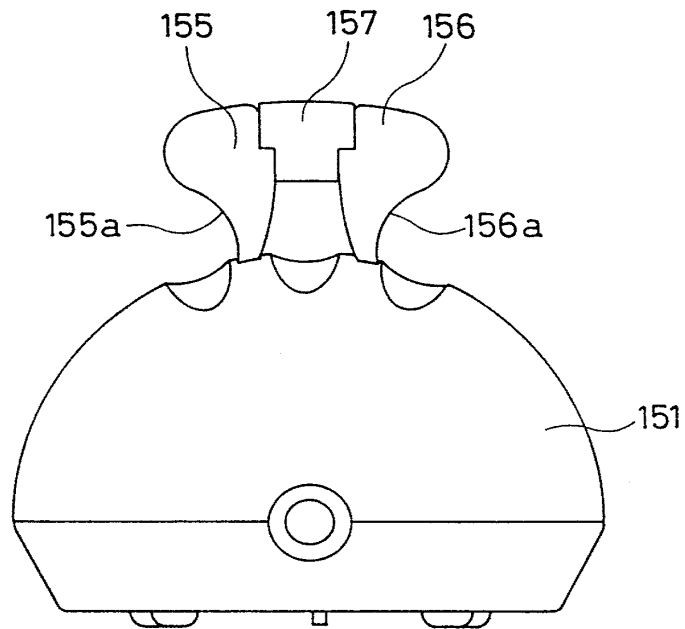
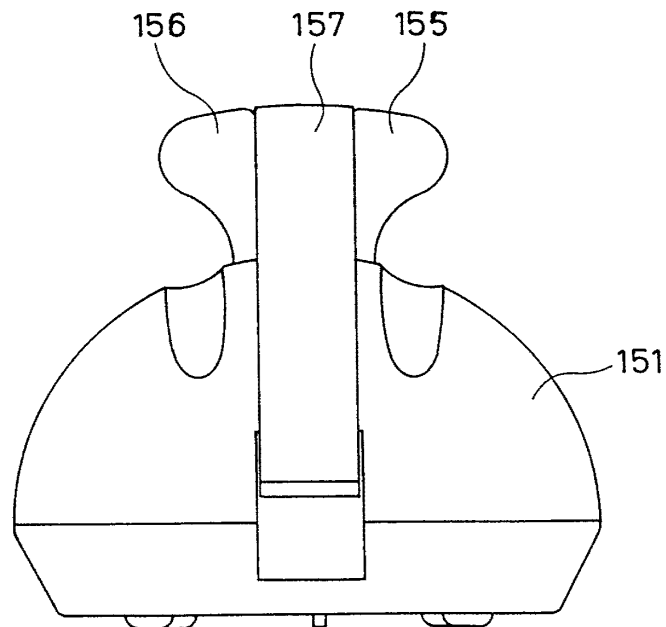


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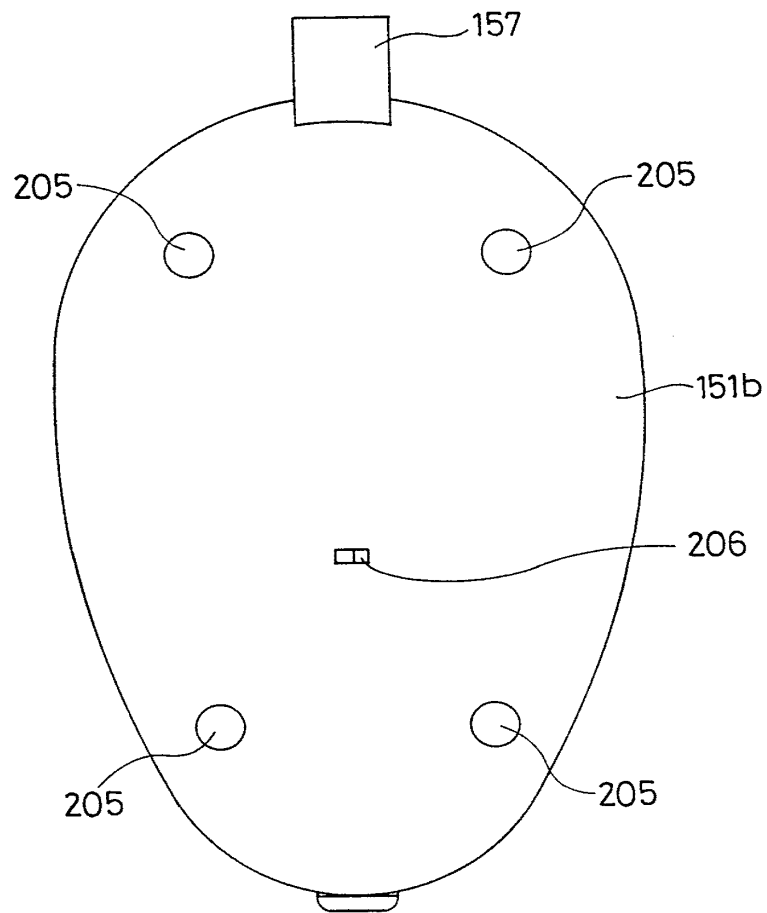


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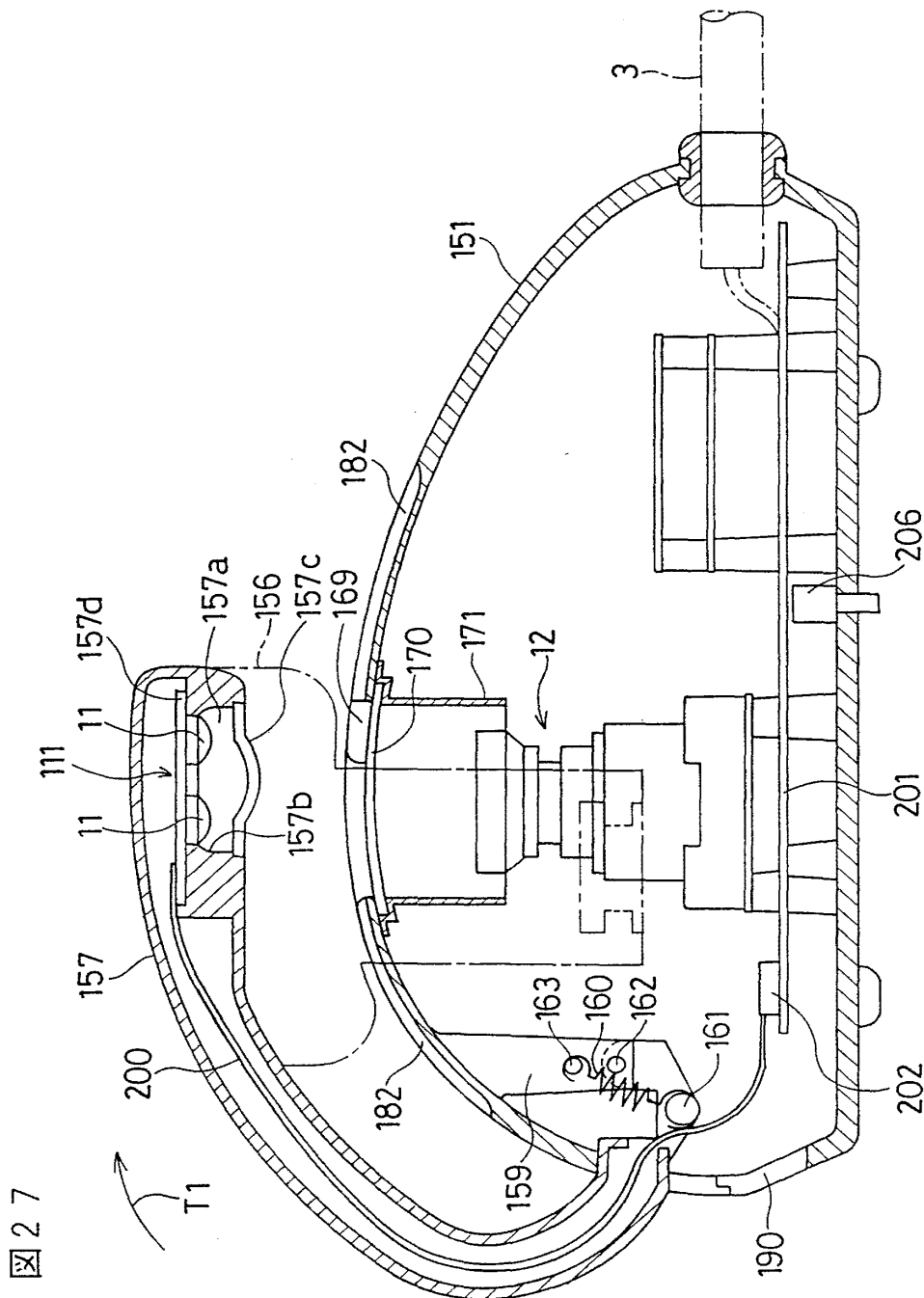
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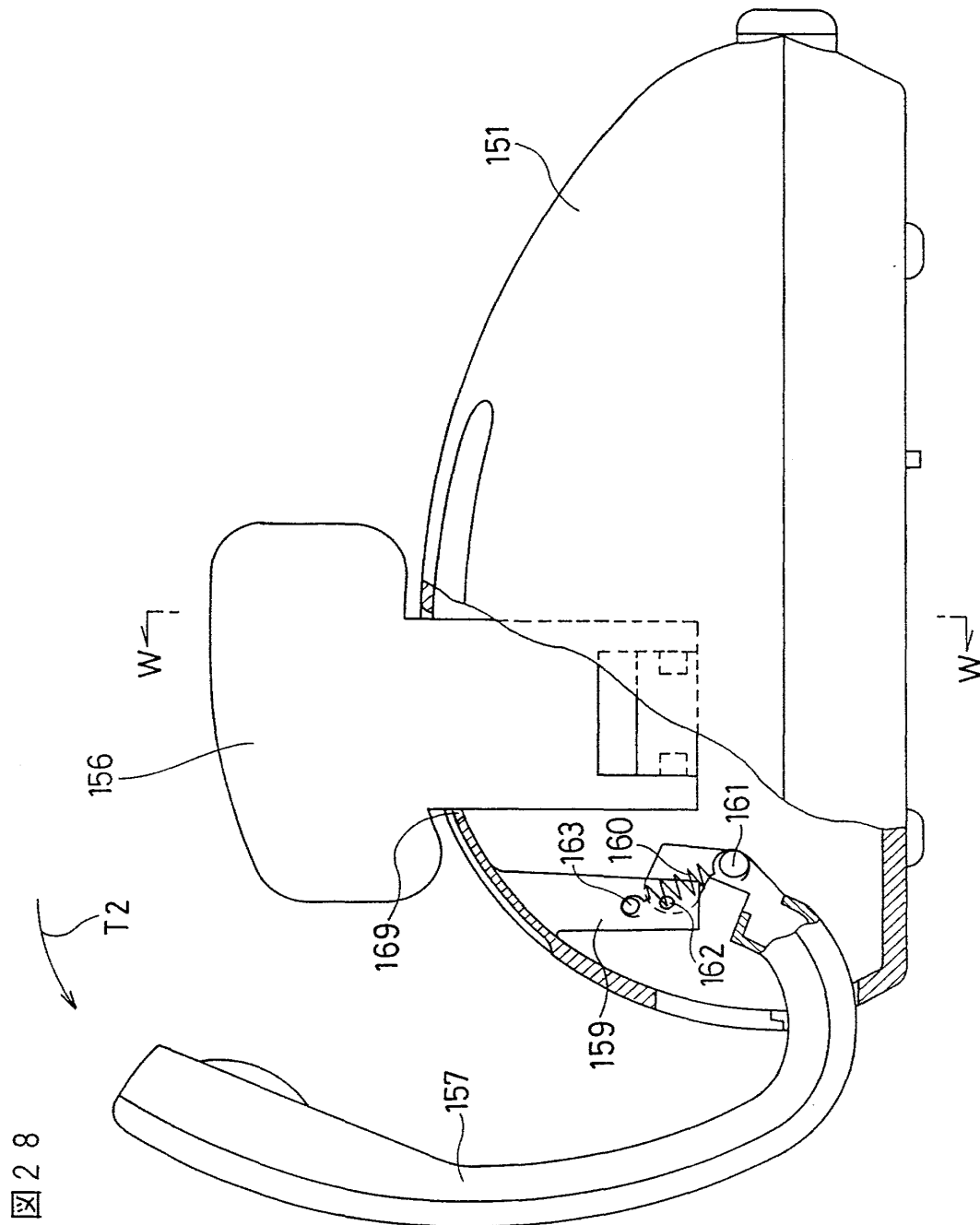
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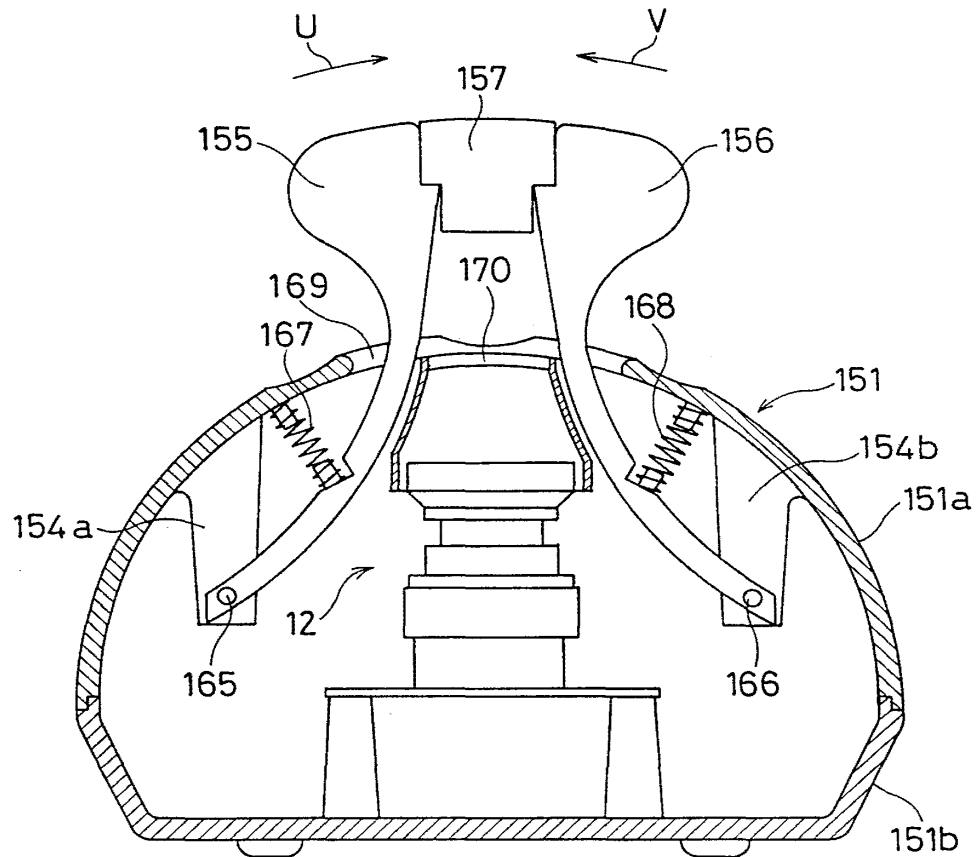
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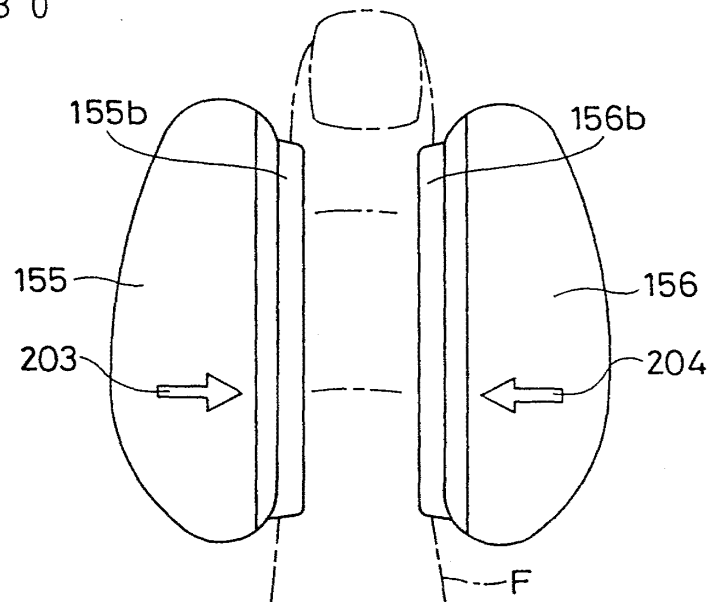
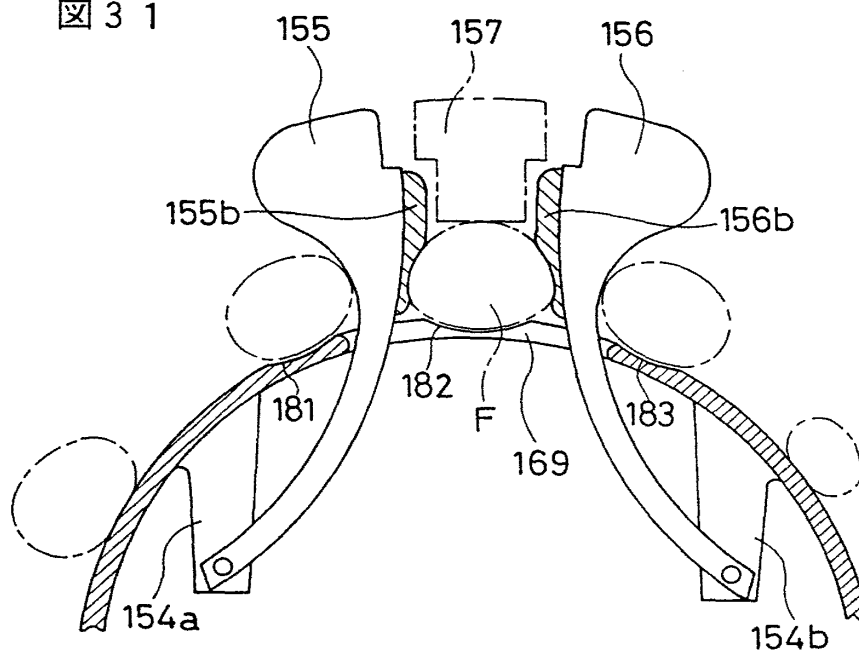


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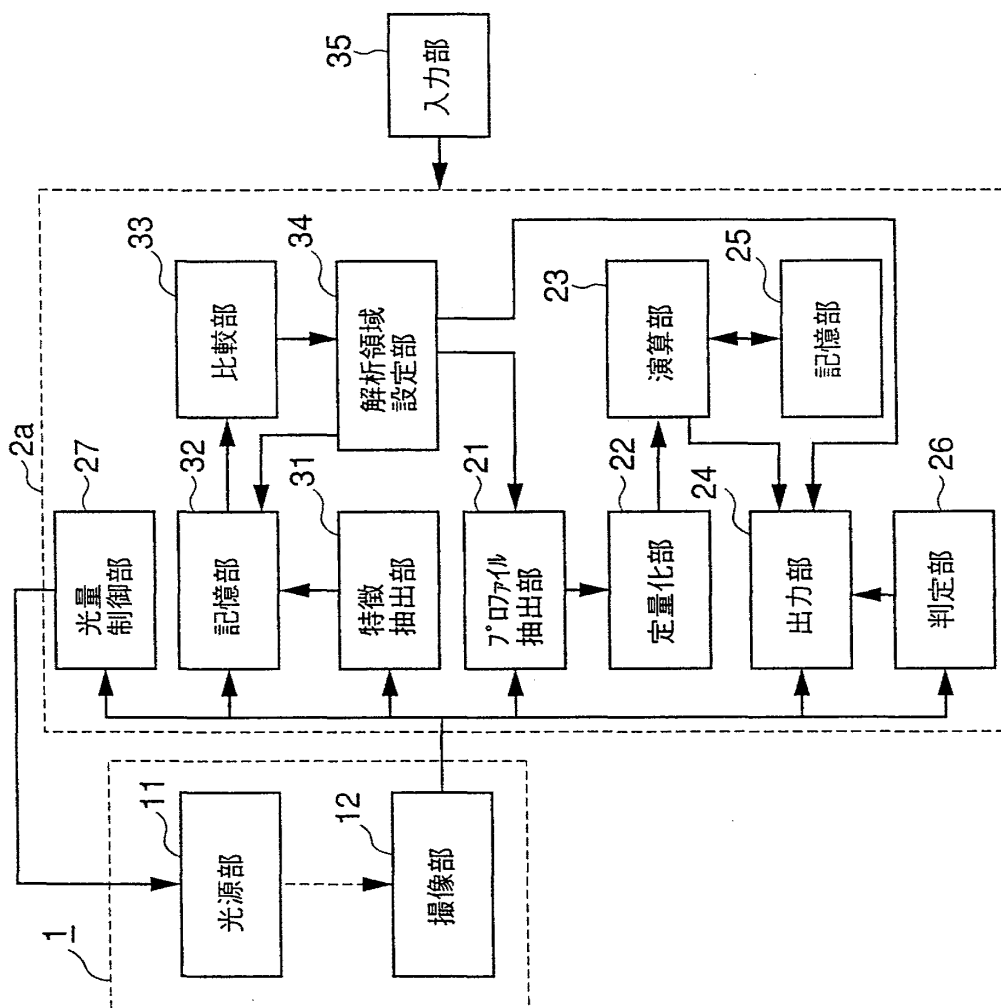


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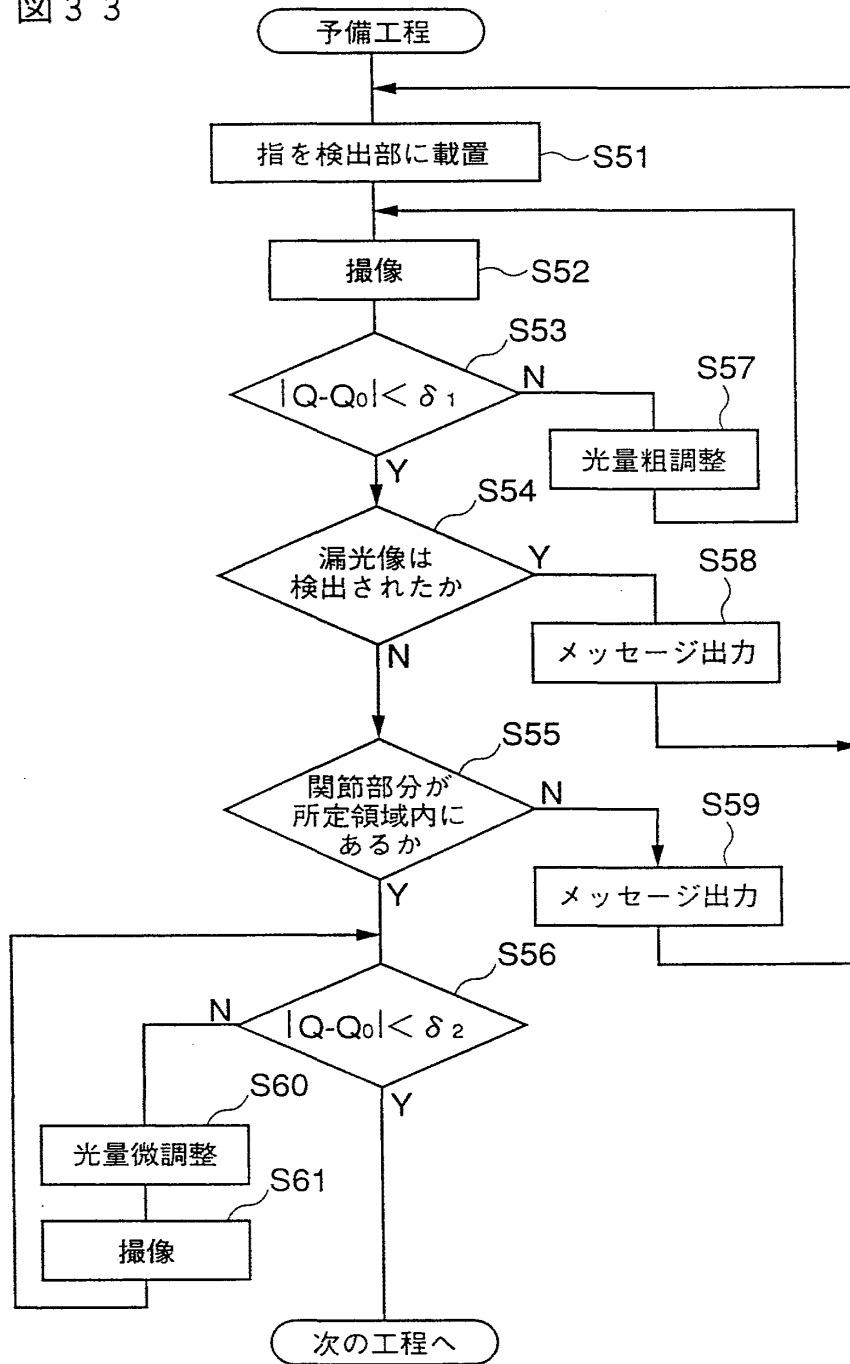


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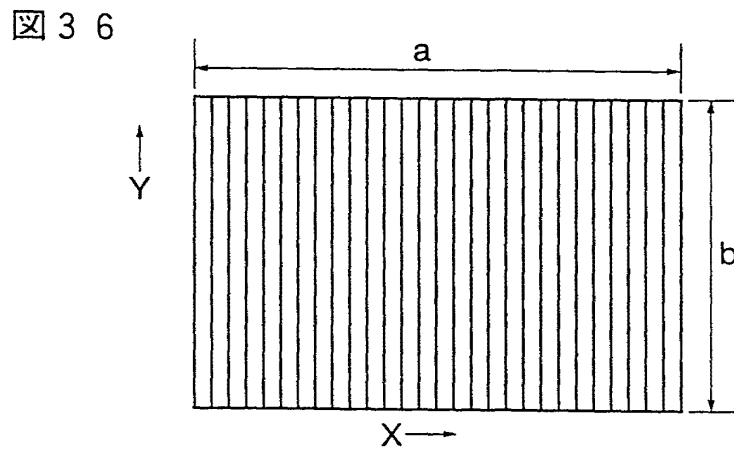
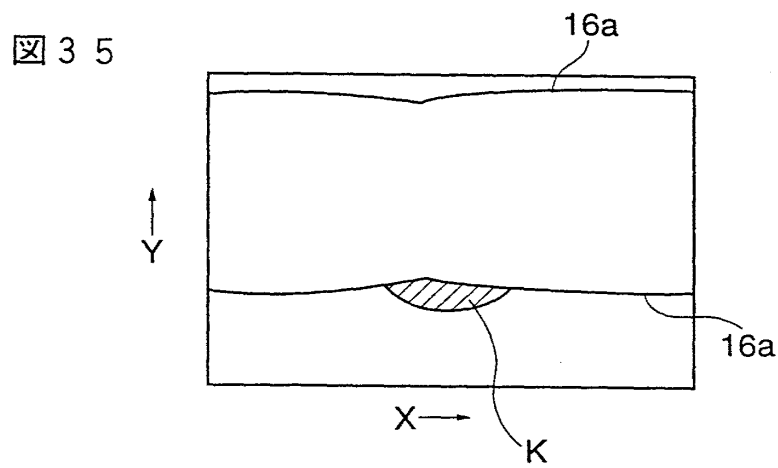
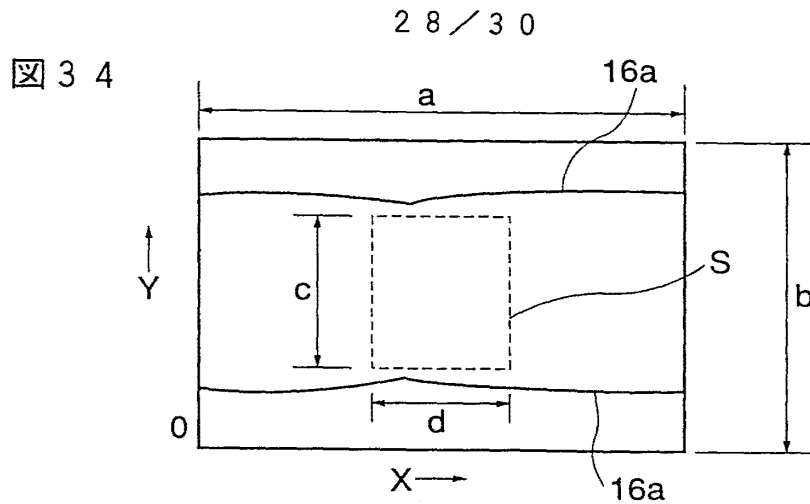
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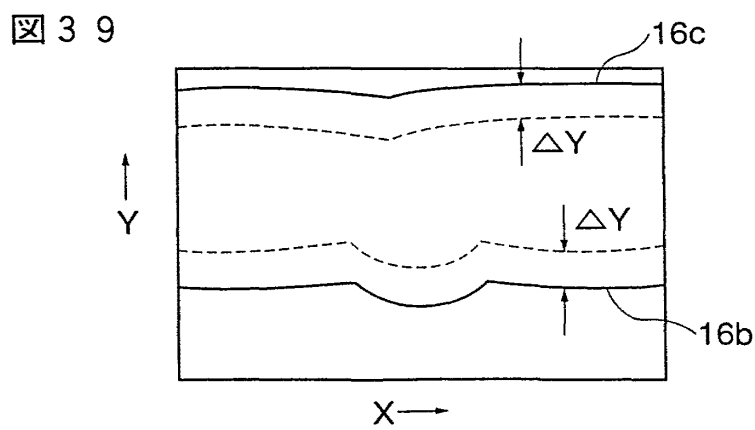
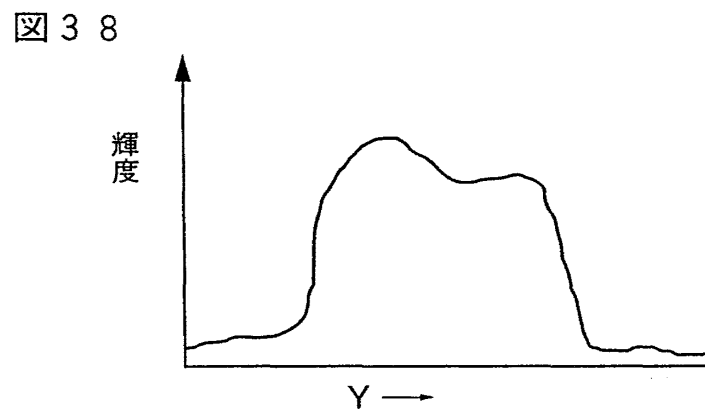
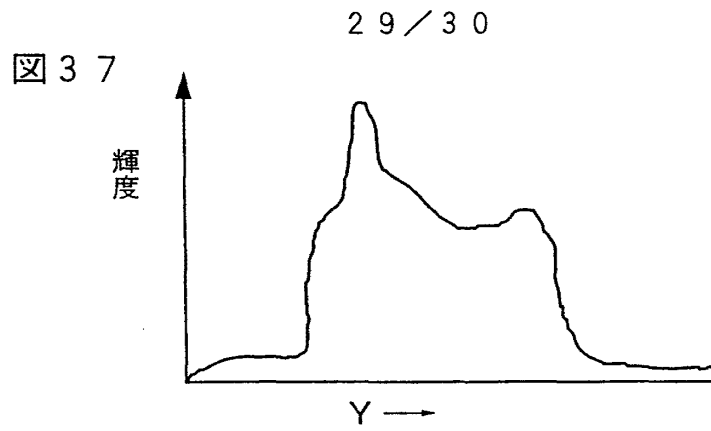
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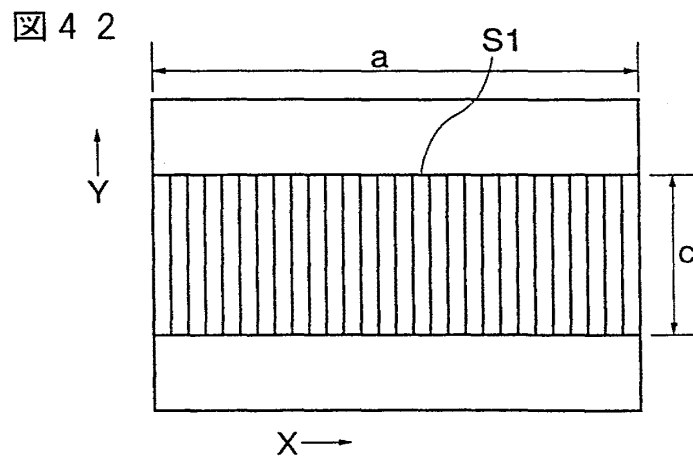
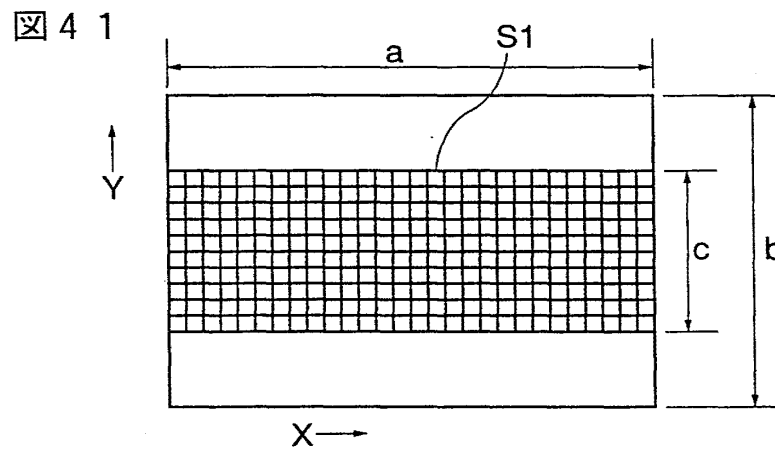
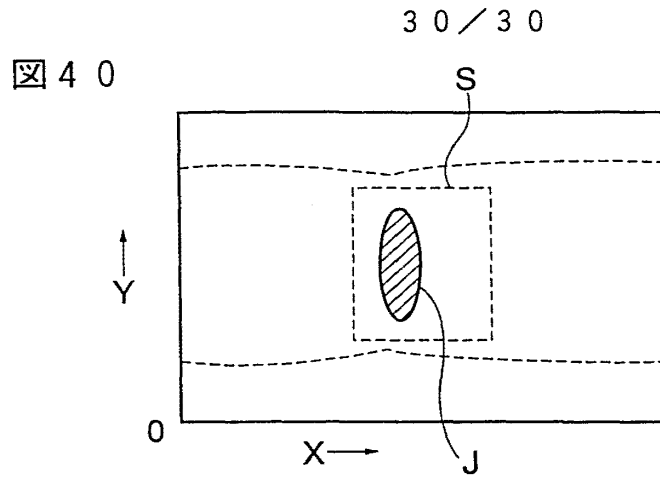
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP98/02875

A. CLASSIFICATION OF SUBJECT MATTER Int.Cl ⁶ A61B5/14, 5/024		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) Int.Cl ⁶ A61B5/14, 5/024		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Jitsuyo Shinan Koho 1945-1997 Toroku Jitsuyo Shinan Koho 1994-1997 Kokai Jitsuyo Shinan Koho 1971-1995		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Microfilm of Japanese Utility Model Application No. 88505/1991 (JP, 3-88505, U) (K.K. Misawa Homu Sogo Kenkyusho), September 10, 1991 (10. 09. 91) (Family: none)	1-22
A	Microfilm of Japanese Utility Model Application No. 39005/1991 (JP, 3-39005, U) (K.K. Misawa Homu Sogo Kenkyusho), April 16, 1991 (16. 04. 91) (Family: none)	1-22
A	Microfilm of Japanese Utility Model Application No. 61309/1990 (JP, 2-61309, U) (Minolta Camera Co., Ltd.), May 8, 1990 (08. 05. 90) (Family: none)	1-22
A	JP, 4-51936, A (OTAX Co., Ltd.), February 20, 1992 (20. 02. 92) (Family: none)	1-22
A	JP, 7-88105, A (Kowa Co., Ltd.), April 4, 1995 (04. 04. 95) (Family: none)	1-22
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
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Date of the actual completion of the international search July 10, 1998 (10. 07. 98)		Date of mailing of the international search report July 21, 1998 (21. 07. 98)
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International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP, 7-213498, A (Matsushita Electric Industrial Co., Ltd.), August 15, 1995 (15. 08. 95) (Family: none)	1-22
A	JP, 6-125881, A (Misawa Homes Co., Ltd.), May 10, 1994 (10. 05. 94) (Family: none)	1-22
A	JP, 6-503728, A (Cadell Theodore E.), April 28, 1994 (28. 04. 94) & WO, 92/3965, A1	1-22
A	JP, 6-505903, A (Mashimo Corp.), July 7, 1994 (07. 07. 94) & WO, 92/16142, A1	1-22

CX-1622

国際調査報告		国際出願番号 PCT/J P 98/02875	
A. 発明の属する分野の分類 (国際特許分類 (IPC))			
Int. Cl ^o A61B5/14, 5/024			
B. 調査を行った分野			
調査を行った最小限資料 (国際特許分類 (IPC))			
Int. Cl ^o A61B5/14, 5/024			
最小限資料以外の資料で調査を行った分野に含まれるもの			
日本国実用新案公報 1945-1997年 日本国公開実用新案公報 1971-1995年 日本国登録実用新案公報 1994-1997年			
国際調査で使用した電子データベース (データベースの名称、調査に使用した用語)			
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国際調査を完了した日 10. 07. 98		国際調査報告の発送日 21.07.98	
国際調査機関の名称及びあて先 日本国特許庁 (ISA/J P) 郵便番号 100-8915 東京都千代田区霞が関三丁目4番3号		特許庁審査官 (権限のある職員) 山本 春樹 印 電話番号 03-3581-1101 内線 3251	

様式PCT/ISA/210 (第2ページ) (1992年7月)

国際調査報告		国際出願番号 PCT/J P 9 8 / 0 2 8 7 5
C (続き) . 関連すると認められる文献		
引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
A	し) JP, 7-213496, A(松下電器産業株式会社) 15. 8月. 1995(15. 08. 95) (フ ァミリーなし)	1 - 2 2
A	JP, 6-125881, A(ミサワホーム株式会社) 10. 5月. 1994(10. 05. 94) (フ ァミリーなし)	1 - 2 2
A	JP, 6-503728, A(カデル、セオドア・イー) 28. 4月. 1994(28. 04. 94) & WO, 92/3965, A1	1 - 2 2
A	JP, 6-505903, A(マシモ・コーポレーション) 7. 7月. 1994(07. 07. 94) & WO, 92/16142, A1	1 - 2 2

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: F25D 11/02	A2	(11) International Publication Number: WO 99/01704 (43) International Publication Date: 14 January 1999 (14.01.99)
(21) International Application Number: PCT/US98/13292 (22) International Filing Date: 26 June 1998 (26.06.98) (30) Priority Data: 60/051,743 3 July 1997 (03.07.97) US (71) Applicant: GENERAL ELECTRIC COMPANY [US/US]; 1 River Road, Schenectady, NY 12345 (US).		(72) Inventors: BAKER, Phillip, D.; 144 Peddlers Court, Mt. Washington, KY 40047 (US). WALKER, Gordon, T.; 8711 Wildon Place, Louisville, KY 40220 (US). MATZ, Dennis, P.; 7501 Stonebrook Drive, Louisville, KY 40291 (US). MITCHELL, Gerald, L.; 5109 Barry Lane, Floyds Knob, IN 47119 (US). MILLER, Joseph, M.; 7409 Russell Avenue, Louisville, KY 40258 (US). STEINER, Mark, W.; 2827 Woods Club Road, Louisville, KY 40241 (US). NELSON, Charles, W.; 10500 Easum Road, Louisville, KY 40299 (US). RUARK, Bruce, L.; 7107 Peppermill Lane, Louisville, KY 40299 (US). MARTIN, Jerry, C.; 4035 Old Forrest Road, Corydon, IN 47112 (US). MCCAULEY, Michael, J.; 4936 Murrays Run Road, Coxes Creek, KY 40013 (US). DOMAGALA, John, J.; 1909 Maxwell Lane East, Bloomington, IN 47401 (US). JUBENVILLE, Duane; 311 Flat Rock Road, Louisville, KY 40245 (US). CSERNIK, Michael, S.; 6268 Mariemont Drive, Louisville, KY 40291 (US). (74) Agent: STECKLER, Henry, I.; General Electric Company, 3135 Easton Turnpike W3C, Fairfield, CT 06431 (US). (81) Designated States: BR, JP, KR, MX, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: MODULAR REFRESHMENT CENTER FOR REFRIGERATOR FRESH FOOD COMPARTMENT		
(57) Abstract <p>A refreshment center (22) positioned in the fresh food compartment door (30) has a modular construction and includes a mini door (42) and a frame (68). The mini door (42) is fabricated and assembled separate from the frame (68), and the mini door (42) includes a hinge system (120) and a trigger (78). The frame (68) includes first and second spaced apart planar members (102, 104), and further includes a keeper slot (106) and a keeper (108) for being inserted within the slot (106). The frame further includes a switch cavity (110) for housing at least a portion of a switch assembly (112). The mini door (42) is secured to the frame (68) by a hinge system (120) which includes a hinge arm (122) which extends between, and is secured to, the mini door (42) and the frame (68). The switch assembly (112) includes a switch (166) having a switch actuator arm (182). The light used to illuminate the refreshment center (22) can be one of the existing lights used in current side-by-side refrigerators since the inner cover (56) is transparent.</p>		

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MODULAR REFRESHMENT CENTER FOR
REFRIGERATOR FRESH FOOD COMPARTMENT

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/051,743, filed July 3, 1997.

FIELD OF THE INVENTION

5 This invention relates generally to household refrigerators and more particularly, to a refreshment centers accessible through a mini door in the main door of a refrigerator fresh food compartment.

BACKGROUND OF THE INVENTION

10 Side-by-side household refrigerators include a fresh food storage compartment and a freezer storage compartment. Each storage compartment has a front access opening normally closed by a fresh food door and a freezer door, respectively. Some refrigerators include intermediate storage compartments (e.g., beverage storage compartment) in the fresh food compartment and accessible without
15 opening the fresh food compartment door. For example, a separate access door may be mounted to the fresh food compartment door, and such access door normally closes a front access opening in the fresh food door. The intermediate storage compartment, sometimes referred to as a refreshment center, is accessible by opening the access door.

20 It would be desirable to improve the appearance, performance, and usefulness of refreshment centers. Of course, in making such improvements, the costs associated with fabrication and assembly of such centers cannot become excessive. For example, in at least some known refreshment centers, the access door is bulky and is not easy to

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open. Further, the hinge systems used with some known access doors form a tight fit with the access door and refrigerator compartment. At least with these known configurations, the bulky door and tight fit of the hinge system are required in order to prevent significant leakage of cooled air through the access opening. The bulky door and tight fit of the hinge system, however, increase the difficulty in cleaning the refreshment center and are not aesthetically pleasing.

SUMMARY OF THE INVENTION

These and other objects may be attained by a refreshment center which has a modular construction and generally, includes a mini door and a frame. The mini door is fabricated and assembled separate from frame, and the mini door includes a hinge system and a trigger latch. The mini door is sized to be mated with a door flange, or trim, and provides quick and convenient access to the refreshment center by being simple and easy to open and close. Further, the mini door is light weight and the hinge system reduces the free drop open speed for quality and safety. When the mini door is in the fully opened position, the mini door provides a surface for simple snack or drink preparation. Also, the mini door hinge system allows easy access for cleaning hard to reach areas. Further, by controlling the gaps between the mini door edges and the surrounding frame, the mini door has an aesthetically pleasing appearance.

The frame, in an exemplary embodiment, is a one piece plastic molded part which serves as the main structural member of the refreshment center. The frame includes first and second spaced apart planar members, and further includes a keeper slot and a keeper for being inserted within the slot. The keeper extends from the slot and at least partially through a keeper slot in the door flange. The frame further includes a switch cavity for housing at least a portion of a switch

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assembly. A switch bracket is provided to be secured over the switch cavity and is engaged to the frame by a bolt.

The mini door is secured to the frame by the hinge system. The hinge system includes hinge arms which extend between, and are secured to, the mini door and the frame. More specifically, at the frame, the hinge arms are secured to slides located between the first and second planar members of the frame. Hinge pins are secured to the mini door outer door member and extend from the outer door member and through the bushings of pivot slides. The pivot slides are secured to the frame by retainers, and springs are provided to maintain the pivot slides in position within the retainer.

The switch assembly includes a switch having a switch actuator arm. Wires extend from the switch to a harness which mates with a receptacle. The receptacle is in electric circuit with a light in the fresh food compartment. The light used to illuminate refreshment center can be one of the existing lights used in current side-by-side refrigerators. Therefore, there is no need for a separate lamp to illuminate the refreshment center, which is believed to reduce the costs and increase the efficiency of a refrigerator incorporating the refreshment center.

The switch assembly also includes a switch actuator having an actuator arm and an actuator block. The actuator arm extends through an opening in a rib between the first and second planar members of the frame. The switch arm extends to a position over the actuator block. When the door is opened, the actuator block rests on the rib and does not engage the switch arm of the switch. As a result, the switch is closed and the fresh food compartment light is energized. As the door is closed, the slide drives the actuator upward so that the actuator block engages and pushes against the switch arm. When the switch arm is so engaged, the switch opens thereby opening the circuit between the switch and the fresh food compartment light.

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As explained above, and for ease of fabrication and assembly, the refreshment center also is modular and easy to install. Specifically, the frame and the mini door are separately fabricated and provided for assembly as pre-assembled modules. The modular construction is
5 believed to reduce the amount of labor required in the assembly process. In addition, good cold storage temperatures are maintained and controlled in the above described refreshment center by venting and guiding cold air from the freezer compartment into the refreshment center chamber. The chamber is enclosed by the inner cover which
10 serves as a separation baffle and encloses the refreshment center space. Also, by eliminating metal hinges and replacing such metal hinges with small metal pivot pins that do not wick heat energy in or out of the refreshment center space, it is believed that refreshment center also is energy efficient.

15 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a side-by-side refrigerator including a refreshment center in accordance with one embodiment of the present invention.

20 Figure 2 is a perspective view of the refrigerator shown in Figure 1 with the fresh food compartment door open.

Figure 3 is an exploded view of components of the refreshment center shown in Figure 1.

25 Figure 4 is a partial cross-sectional view through a section of the refreshment center shown in Figure 1 and illustrating the latch mechanism.

Figure 5 is a partial cross-sectional view through a section of the refreshment center shown in Figure 1 and illustrating the light actuation system.

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Figure 6 is a partial cross-sectional view through a section of the refreshment center shown in Figure 1 and illustrating a portion of the hinge system.

5 Figure 7 is a partial cross-sectional view through a section of the refreshment center shown in Figure 1 and illustrating the hinge system.

Figure 8 is a partial cross-sectional front view through a section of the mini door.

Figure 9 is a partial cross-sectional side view through a section of the mini door.

10 Figure 10 is a side view of a portion of the assembled refreshment center.

DETAILED DESCRIPTION

An exemplary embodiment of a refreshment center is described below in detail in connection with a side-by-side household refrigerator. 15 Side-by-side household refrigerators are commercially available from General Electric Company, Louisville, Kentucky, 40225, and such refrigerators can be modified to incorporate the refreshment center. The refreshment center, of course, can be used in many other models and types of refrigerators other than the specific side-by-side refrigerator described herein. 20

Figure 1 is a perspective view of a side-by-side refrigerator 20 including a refreshment center 22 in accordance with one embodiment of the present invention. Refrigerator 20 includes a cabinet 24 having a fresh food storage compartment 26 and a freezer storage 25 compartment 28 arranged in a side-by-side configuration. Each storage compartment 26 and 28 has a front access opening normally closed by a fresh food door 30 and a freezer door 32, respectively. Each door 30 and 32 is secured to compartment cabinet 24 by a hinge

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34, and handles 36 and 38 are mounted to each door 30 and 32 to facilitate door opening. Freezer door 32 includes a through-the-door dispensing mechanism 40 for dispensing, for example, ice and water. In accordance with the present invention, refrigerator 20 also includes
5 refreshment center 22 accessible through an access opening in fresh food door 30. The access opening is closed by a mini door 42.

Figure 2 is a perspective view of refrigerator 20 with fresh food compartment door 30 open. Fresh food compartment 26 has adjustable shelves 44 and lower drawers 46. In addition, an inner
10 member 48 of fresh food door 30 supports shelves 50 and a butter or cheese compartment 52. Freezer compartment 28 typically includes shelves and baskets to store items and the inner member of freezer door 32 supports shelves to store additional items.

Refreshment center 22 includes a shelf 54 which receives an
15 inner cover 56. An access opening cover 58 is secured to inner cover 56, and access opening cover 58 is hingedly secured to inner cover 56 so that access opening cover 58 can be rotated relative to inner cover 56 to allow access to items stored on shelf 54. Inner cover 56, along with shelf 54 and shelf 60, define an area or chamber for the storage of
20 items within refreshment center 22. Items stored within this area are accessible through mini door 42 (Figure 1). In addition, when fresh food door 30 is opened, items within this area are accessible through access opening cover 58. Also, items within fresh food compartment 26 are accessible through mini door 42 and access opening cover 58
25 when fresh food door 30 is closed.

To cool items stored in the refreshment center chamber, an air flow opening 62 is provided in inner cover 56, and when fresh food door 30 is closed, air flows through opening 62 and into the refreshment center chamber from a vent 64 in flow communication with

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freezer compartment 28. A damper may be located in vent 64 to control the flow of cooler freezer air to within the refreshment center.

Figure 3 is an exploded view of components of refreshment center 22. Generally, refreshment center 22 includes mini door 42, a door flange or trim 66, a frame 68, a gasket 69, and inner cover 56. Mini door 42 and door trim 66 are generally positioned at the external surface of cabinet 28 and frame 68 and inner cover 56 are positioned within cabinet 24. An access opening 70 is provided so that a user, when mini door 42 is open, can access items stored in refreshment center 22.

Mini door 42 includes an outer door member 72 and an inner door member 74. Inner door member 74 is sized to partially extend through opening 70. A handle 76 is secured to outer door member 72, e.g., by a slip fit with notch engagement, and a trigger 78 is secured to outer door member 72 by hinge pins 80 which extend through opening 82 in flanges 84 of handle 76. Trigger 78 includes a grip 86, leaf springs 88, and a pusher member 90 which, as described below in more detail, cooperate to provide for easy opening and closing of mini door 42.

Door trim 66 includes an inner flange 92 sized to extend around the periphery of access opening 70 and an outer flange 94 which extends substantially flush with the outer surface of door 30. Gasket 69 includes an inner surface 95 which forms a tight fit around trim inner flange 92. Trim 66 is snap fit into place on door 30. Specifically, pins (not shown) extend from an inner surface 96 of outer flange 94 and such pins align with clips in door 30. When snapped into place, trim 66 is securely held in place and supported by door 30. Door trim 66 also includes a keeper slot 98 and pivot slots 100 which, as described below in more detail, facilitate opening and closing of mini door 42.

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Frame 68 is a one piece plastic molded part which may be molded, for example, from ABS plastic (type Hybrid B) commercially available from Monsanto Company, St. Louis, Missouri. Frame 68 includes first and second spaced apart planar members 102 and 104. A keeper slot 106 is located in first member 102 and a keeper 108 is provided for being inserted within slot 106. Keeper 108 extends from slot 106 and at least partially through keeper slot 98 in door trim 66. Frame 68 further includes a switch cavity 110 for housing at least a portion of a switch assembly 112. A switch bracket 114 is provided to be secured over opening 116 of switch cavity 110 and is engaged to frame 68 by a screw 118.

Mini door 42 is secured to frame 68 by a hinge system 120 which includes hinge arm 122 which extends from mini door 42 to frame 68. Specifically, hinge arm 122 has two ends 124 and 126, and openings 128 and 130 are formed in respective ends 124 and 126. A bracket 132 is secured to inner door member 74 by a screw 134 and a stop member 138, and hinge arm is secured to bracket 132 by a rivet 136. Stop member 138 limits the rotation of mini door 42 by engaging hinge arm 122 once mini door 42 has been rotated to the fully open position. Although not shown in Figure 3, a similar hinge arm assembly is secured to the opposing side of inner door member 74.

Hinge arm 122 also is secured to a slide 140 located between first and second planar members 102 and 104 of frame 68. Specifically, a stud 142 extends through second opening 128 in hinge arm 122, through a slide slot 144 in frame 68, through a nut 146, and into threaded engagement with slide 140. A connector cap 148 with a slot 150 formed therein is slid over second end 124 of hinge arm 122 and covers the head of nut 146. A cap 152 is positioned over slide 140 and cap 152 prevents foamed-in-place insulation from filling the space in which slide 140 is required to move to allow opening and closing of mini door 42.

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Hinge pins 154 (only one hinge pin 154 is shown in Figure 3) are secured to mini door outer door member 72 and extend from outer door member 72 and through bushings 156 of pivot slides 158. Pivot slides 158 are secured to frame 68 by retainers 160 bolted by bolts 162 to frame 68, and springs 164 are provided to maintain pivot slides 158 in position within retainer 160 as described below in more detail.

Switch assembly 112 includes a switch 166 having a switch arm 168. Wires 170 extend from switch 166 to a harness connector 172 which mates with a receptacle 174. Receptacle 174 is in electric circuit with a light in fresh food compartment 26. The light used to illuminate refreshment center 22 can be one of the existing lights used in current side-by-side refrigerators since inner cover 56 is transparent. Therefore, there is no need for a separate lamp to illuminate refreshment center 22, which is believed to reduce the costs and increase the efficiency of a refrigerator incorporating refreshment center 22.

Wires 170 extend through a spacer member 176 configured to be inserted into, and securely held within, a slot (not shown) in frame 68 formed by ribs (not shown) extending between first and second planar members 102 and 104. A switch cover 178 is sized to be inserted between first and second planar members 102 and 104 and over switch 166 so that foamed-in-place insulation does not fill up cavity 110 and prevent proper operation of switch 166.

Switch assembly 112 also includes a switch actuator 180 having an actuator arm 182 and an actuator block 184. Actuator arm 182 extends through an opening in a rib 186 between first and second planar members 102 and 104. Arm 168 extends to a position below actuator block 184.

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When door 42 is open, actuator block 184 rests on rib 186 and does not engage switch arm 168. As a result, switch 166 is closed and the fresh food compartment light is energized. As door 42 is closed, bolt 142 slides upward within slide slot 144 in frame 68 and slide 140 moves upward with bolt 142. As slide 140 moves upward, slide 140 drives actuator 180 upward so that actuator block 184 engages and pushes against switch arm 168. When switch arm 168 is so engaged, switch 166 opens thereby opening the circuit between switch 166 and the light positioned in fresh food compartment 26.

With respect to securing frame 68 within fresh food door 30, first planar member 102 is configured to be positioned against the inner surface of the outer door wall of door 30 and at least is initially loosely secured thereto by plastic push-in headed studs which are pushed through openings in the outer metal wall of fresh food door 30. Specifically, the studs are pushed through the outer wall and openings 188 in frame 68 are aligned with the studs. Frame 68 is then pushed onto the studs so that the studs are at least partially inserted into frame openings 188. Once frame 68 is so positioned, aluminum tape is applied across the interface between the surfaces of first planar member 102 and the inner surface of the door outer wall. The aluminum tape seals against foam leaks flowing perpendicular to the frame edges. The aluminum tape also serves as a heat conductor to prevent or reduce external sweat on frame 68 in high temperature, high humidity kitchens.

Foam blocks are then positioned between frame 68 and the door side flanges near the frame top corners. The foam blocks separate and vent the flow of foam coming from above and below frame 68. Once the foam is poured onto the inner surface of the outer fresh food door wall above and below the framed opening, the foam fixture closes down over second planar member 104 of frame 68. As the foam fixture lid closes, the top side metal inner support is dropped

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into the correct location and position. The foam expands, including into spaces between first and second planar members 102 and 104, and securely holds frame 68 between the outer and inner walls of fresh food door 30.

5 Frame 68 may include ridges and cavities molded into first and second planar members 102 and 104. The cavities serve as collectors and traps for small amounts of foam that may squeeze through between any spaces along the joints where the frame faces lay against fresh food outer door wall. As the foam flow is restricted by a first
10 ridge, it will be slowed or stopped. The small amount of foam that squeezes through then will freeze off upon entering the cavities with more room to increase flow or growth after the flow restriction.

Figure 4 is a partial cross-sectional view through a section of refreshment center 22 shown in Figure 3 and illustrating cooperation
15 between trigger 78 and keeper 108. As described above, trigger 78 includes leaf springs 88 and push member 90. Push member 90 extends through an opening 190 in handle 76 and into contact with a keeper arm 192 of keeper 108. Keeper 108 is snapped into slot 106 in frame 68.

20 When a user pulls grip 86, trigger 78 rotates on pin 80 and push member 90 forces keeper arm 192 out of opening 190 so that mini door 42 can be rotated away from keeper 108. When door 42 is closed, keeper arm 192 snaps over handle opening 190 and keeper 108 maintains door 42 closed until a user once again pulls grip 86.
25 Trigger 78 is simple to operate with low release and keeper 108 forces. Trigger 78 therefore is believed to be easy to use by children and elderly users.

As also shown in Figure 4, pins 194 extend from an inner surface 196 of door trim 66 and such pins 194 snap into engagement

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with receptacles 198 in outer wall 200 of fresh food door 30. Foamed-in-place insulation 202 also is shown in Figure 4 and at least partially illustrates the manner in which frame 68 is securely held in place in door 30.

5 Figure 5 is a partial cross-sectional view through a section of refreshment center 22 and illustrating the light actuation system. As described above, switch assembly 112 includes switch 166 having switch arm 168. Switch 166 is electrically connected in parallel with a fresh food compartment door switch (not shown) to a light positioned in
10 the fresh food compartment. Generally, when the fresh food compartment door is opened, the fresh food compartment door switch closes so that the light is energized, and when the fresh food compartment door is closed, the circuit between the door switch and the light is opened. Similarly, and with respect to switch 166, when
15 mini door 42 is opened, switch 166 closes so that the light is energized, and when mini door 42 is closed, switch 166 opens so that the circuit between switch 166 and the light is opened.

As shown in Figure 5, arm 168 extends over actuator block 184 of switch actuator 180. When door 42 is closed, actuator block 184
20 engages switch arm 168 and switch 166 is open. When door 42 is opened, and as slide 140 moves downward, actuator block 184 rests on rib 186 and does not engage switch arm 168. As a result, switch 166 is closed and the fresh food compartment light is energized.

An actuator ball 204 of actuator arm 182 makes contact with
25 slide 140. Actuator arm 182 extends through an opening 206 in rib 186 so that ball 204 may contact slide 140. Slide 140 is located in a slide slot 208 formed by elongate members 210 and 212 of frame 68. Guides 214 contact members 210 and 212 and stiffening ribs 216 extend between members 210 and 212, to provide more controlled
30 opening and closing of door 42.

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Figure 6 is a partial cross-sectional view through a section of refreshment center 22 and illustrating a portion of hinge system 120. As shown in Figure 6, hinge pin 154 extends from outer door member 72 and into bushing 156 of pivot slide 158. Bushing 156 is located in pivot slot 100 in frame 68, and as described below in more detail, bushing 156 travels within slot 100 when mini door 42 is moved to a cleaning position. Of course, hinge pin 154 rotates relative to bushing 156 when mini door 42 is opened and closed. A spacer 218 extends from a flange 220 of pivot slide 158, and spacer 218 ensures proper spacing between mini door 42 and pivot slide 158.

Hinge system 120 provides that mini door 42 is easy to open and can serve as a stable flat service for pouring drinks or preparing snacks. Also, hinge system 120 is mostly internally located within refreshment center 22 to reduce the possibility of pinching. Further, by minimizing the number of metal fasteners used in connection with mini door 42 the amount of heat conducted into refreshment center cavity is believed to be low. In addition, hinge system 120 provides a flush finished appearance between mini door 42 and refrigerator fresh food door 30.

Figure 7 is a partial cross-sectional view through a section of refreshment center 22 and illustrating hinge system 120. In Figure 7, mini door 42 is shown in the fully opened normal operating position in solid lines and in a cleaning position in phantom. As described above, hinge arm 122 extends between, and is coupled to, mini door 42 and frame 68. Stop 138 prevents rotation of mini door 42 beyond the illustrated fully opened position by limiting movement of hinge arm 122 beyond the position as shown. Further, a spring retainer 222 is secured to outer wall 200 of door 30 by extending a lip 224 of retainer 222 through a slot in wall 200. Spring retainer 222 facilitates maintaining retainer in position with respect to pivot bushing.

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To move mini door 42 to the cleaning position, door 42 is fully opened as illustrated in solid lines and then pushed upward. As door 42 is pushed upward, slide 140 travels upward along with arm 122 and pivot bushing 156 travels upward in pivot slot 100. As bushing 156 travels upward, it snaps over a retainer flange 226 in slot 100 and is held over flange 226 by spring 164. An arm 228 of spring 164 is trapped between outer wall 200 of fresh food door 30 and frame 68 so that spring 164 is securely held in place. By pushing against bushing 156, spring 164 facilitates maintaining bushing 156 above retainer flange 226 while an operator cleans the space between mini door 42 and trim 66. Once the desired cleaning is completed, the operator simply pushes downward on mini door 42 with sufficient force to overcome the retention force of spring 164 and so that bushing 156 snaps over retainer flange 226. Pivot bushing 156 then travels downward and back into retainer 160 for normal operations. Enabling such easy cleaning of typically difficult to reach areas is believed to be pleasing to users and enhances the appearance of refreshment center 22.

Figure 8 is a partial cross-sectional front view through a section of mini door 42. As clearly shown in Figure 8, mini door 42 is filled with foamed-on-place insulation 228. An internal bracket assembly 230 is located within the chamber defined by inner door member 74, and internal bracket assembly 230 includes a bar 232 which extends substantially across the entire length of inner door member 74. At each opposing end of bar 232 (only one end of bar is shown in Figure 8), a retainer assembly 234 is provided. Retainer assembly 234 is secured to bar 232 by a slide member 236 which is movable relative to bar 232 to enable automated location of internal bracket assembly 230 within the inner door member chamber as described below. Retainer assembly 230 includes a channel member 238, and metal nut strip 240 is secured to a chamber wall 242 by positioners 244. When retainer

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assembly 234 is slid into contact with an inner surface 246 of inner door member 74, metal nut strip 240 provides a backing for bolt 134 and stop 138 which extend through inner door member 74 and engage bracket 132 to inner door member 74.

5 As also shown in Figure 8, a plastic spacer 248 is provided between hinge arm 122 and bracket 132 to enable low friction movement of hinge arm 122 relative to mini door 42. Further, a hinge pin extension 250 extends from channel member 238 and is provided to securely retain hinge pin 154 in place. Specifically, hinge pin 154 is
10 secured to outer door member 72 and extends through openings in outer door wall 252, extension and a rib 254. Hinge pin 154 abuts against a rib 256, and in this manner, hinge pin 154 is securely held in place.

Figure 9 is a partial cross-sectional side view through a section
15 of mini door 42. Bolts 134 and 138 extend into nut strip 240 and securely maintain bracket 132 in place. In addition, extension 250 from channel member 236 is provided to add extra strength for maintaining hinge pin 154 in place.

Mini door 42 is fabricated using substantially automated
20 processes combined with a twin sheet thermoforming process. Specifically, a mold is provided to form the interior cavity of inner door member 74 using a plug assist and vacuum forming process. That is, a heated plastic sheet (e.g., ABS type 752 and/or Centrex 833, commercially available from the Monsanto Company) is located
25 between a lower tool and plug, and the lower tool is moved upward toward the plug so that the plug forces the heated plastic metal sheet to conform to the cavity defined by the tool. Bracket assembly 230 is located within channels in the plug, and once the plug deforms the plastic sheet to the lower tool defined cavity, bracket assembly 230 is
30 expanded in the cavity so that retainer assembly 234 is located as

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shown in Figure 8. Specifically, retainer assembly 234 is ratcheted out and cannot be retracted without excessive force. The assembly also is maintained in place by protrusions/bumps cammed into the interior portion of the thermoformed surface over which the retainer is expanded. Extension 250 also cooperates with inner door member 74 to facilitate retaining assembly 230 in place. The plug is then removed from within the cavity. Outer door member 72 is molded from a plastic sheet (e.g., ABS type 752 and/or Centrex 833) using an upper tool and vacuum assist, and once outer door member 72 is formed, the lower tool is raised up to the upper tool and a heat weld is formed between inner door member 74 and outer door member 72. During the welding process, the edges are trimmed and deburred (i.e., flash is removed), and the assembly is then located in a fixture so that holes can be drilled into the sides of inner door member 74 and channel member 238 for bolt 134 and stop 138. Hinge arm 122 is then installed. Vent holes may then be drilled in the assembly and insulation foam is then injected into the chamber defined by outer and inner door members 72 and 74. The foam is allowed to stabilize for approximately about twenty-four hours. The assembly is then transported to a hinge pin drilling station, and the hinge pin holes are then drilled into outer door member 72, extension 250, and rib 254. Excess material also is routed off at this time. Hinge pins 154 are then press fit into position as shown in Figure 8. Trigger 78, handle 76, pivot slides 158, and trim 66 are then secured to the door assembly, and a gasket is secured (e.g., taped) to door 42. Nuts 146 and connector caps 148 also are secured to hinge arm 122. For shipping, a spacer is located between trim 66 and door 42 to facilitate assembling mini door 42 to frame 68.

As described above, by enabling separate fabrication of mini door 42 from frame 68, mini door 42 can be substantially independently fabricated and delivered to the assembly site for

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installation into a refrigerator. Such modular assembly provides many advantages as discussed above.

Figure 10 is a side view of a portion of assembled refreshment center 22. As shown in Figure 10, inner cover 56 includes top side flaps 258 that fit into pockets 260 in a bottom portion of shelf 60. Inner cover 56 also includes lower flanges 262 that cooperate with shelf 54 to maintain inner cover 56 in position. Access opening cover 58 is hingedly secured, by integral hinge pins 264, to inner cover 56 so that access opening cover 58 can be rotated relative to inner cover 56 to allow access to items stored on shelf 54. Inner cover 56, along with shelf 54 and shelf 60, define the refreshment center storage chamber for the storage of items within refreshment center 22. Items stored within this chamber are accessible through mini door 42. In addition, when fresh food door 30 is opened, items within this chamber are accessible through access opening cover 58. Air flow opening 62 is provided in inner cover 56, and when fresh food door 30 is closed, air flows into the refreshment center chamber from vent 64 in flow communication with freezer compartment 28.

Inner cover 56 reduces the loss of chilled air when mini door 42 is opened and closed. In addition, inner cover 56 facilitates the collection of cold air from the freezer compartment to lower and improve temperature maintenance in the refreshment center compartment.

The above described refreshment center is believed to provide many advantages over known centers. For example, the mini door provides quick and convenient access by being simple and easy to open and close. Further, the mini door is light weight and the hinge system reduces the free drop open speed for quality and safety. When the mini door is in the fully opened position, the mini door provides a surface for simple snack or drink preparation. The mini door work

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surface may be contoured to facilitate catching spills. Also, the mini door hinge system allows easy access for cleaning hard to reach areas. Further, by controlling the gaps between the mini door edges and the surrounding frame, the mini door has an aesthetically pleasing appearance.

For ease of fabrication, the refreshment center also is modular and easy to install. Specifically, the mini door frame and the mini door can be separately fabricated and provided for assembly as pre-assembled modules. The mini door frame assembly can be pre-assembled except for the keeper. The mini door, trim and gasket assembly also are pre-assembled. Just prior to final fresh food door assembly, the latch keeper is located in the slot in keeper slot and the mini door is assembled to the mini door frame previously foamed-in-place. This modular construction is believed to reduce the amount of labor required in the assembly process.

Moreover, good cold storage temperatures are maintained and controlled by venting and guiding cold air from the freezer compartment into the refreshment center chamber. The chamber is enclosed by the inner cover which serves as a separation baffle and encloses the refreshment center space. The inner cover can be easily and quickly installed without requiring the removal of any shelves on the inner door member. By eliminating metal hinges and replacing such metal hinges with small metal pivot pins that do not wick heat energy in or out of the refreshment center space, it is believed that refreshment center also is energy efficient. Also, the trigger, latch, and handle are metal and fastener free, which provides additional energy savings.

From the preceding description of various embodiments of the present invention, it is evident that the objects of the invention are attained. Although the invention has been described and illustrated in

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detail, it is to be clearly understood that the same is intended by way of illustration and example only and is not to be taken by way of limitation. Accordingly, the spirit and scope of the invention are to be limited only by the terms of the appended claims.

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WHAT IS CLAIMED IS:

1. A side-by-side refrigerator comprising a cabinet having a fresh food storage compartment and a freezer storage compartment, said fresh food storage compartment comprising a front access opening normally closed by a fresh food door, and a refreshment center accessible through an access opening in said fresh food door, said refreshment center comprising a modular mini door for closing said access opening in said fresh food door, a frame secured between outer and inner walls of said fresh food door, and a hinge system for securing said mini door to said frame.
2. A refrigerator in accordance with Claim 1 wherein said refreshment center further comprises an inner cover and a shelf, said inner cover supported by said shelf and comprising an access opening, an access opening cover secured to said inner cover and normally closing said access opening cover.
3. A refrigerator in accordance with Claim 2 wherein said inner cover further comprises an air flow opening therein so that air may flow into a refreshment center chamber from a vent in flow communication with said freezer compartment.
4. A refrigerator in accordance with Claim 1 further comprising door trim secured to said fresh food door at said access opening in said fresh food door.
5. A refrigerator in accordance with Claim 1 wherein said mini door comprises an outer door member and an inner door member, said inner door member sized to partially extend through said access opening in said fresh food door.
6. A refrigerator in accordance with Claim 6 further comprising a handle secured to said outer door member and a trigger

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secured to said outer door member, said trigger comprising a grip, at least one leaf springs, and a pusher member.

7. A refrigerator in accordance with Claim 1 wherein said frame comprises first and second spaced apart planar members, a keeper slot in first member, and a switch cavity for housing at least a portion of a switch assembly.

8. A refrigerator in accordance with Claim 1 wherein said hinge system comprises a hinge arm secured to said mini door and to said frame.

9. A refrigerator in accordance with Claim 8 comprising a bracket secured to said mini door, and said hinge arm is secured to said bracket, said hinge system further comprising a stop member secured to said bracket and positioned to limit rotation of said mini door.

10. A refrigerator in accordance with Claim 8 wherein said hinge arm is secured to a slide located between said first and second planar members of said frame, and a cap positioned over said slide.

11. A refrigerator in accordance with Claim 8 wherein said hinge system further comprises hinge pins secured to said mini door, and pivot slides secured to said frame, said pivot slides comprising bushings, and said hinge pins extending into respective bushings.

12. A refrigerator in accordance with Claim 1 further comprising a switch assembly comprising a switch having a switch arm, said switch in electric circuit with a light, and a switch actuator having an actuator arm and an actuator block.

13. A method for fabricating a refreshment center for a refrigerator comprising a cabinet having a fresh food storage

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compartment and a freezer storage compartment, said method comprising the steps of:

fabricating a fresh food door having a refreshment center frame between inner and outer walls of the door;

- 5 fabricating a mini door for closing an access opening defined by the refreshment center frame; and
 securing the mini door to the frame.

14. A method in accordance with Claim 13 wherein fabricating the fresh food door comprises the steps of:

- 10 positioning a first planar member of the frame on an inner surface of an outer door wall of the door;

 locating aluminum tape across interfaces between the first planar member and the inner surface of the door outer wall;

- positioning foam blocks between the frame and the door side
15 flanges;

 pouring foam onto the inner surface of the outer fresh food door wall above and below the framed opening;

- closing a foam fixture over a second planar member of the frame and, as the foam fixture lid closes, locating a top side metal
20 inner support over the frame.

15. A method in accordance with Claim 13 wherein fabricating the mini door comprises the steps of:

 molding an inner door member using a plug assist and vacuum forming process;

- 25 molding an outer door member using a vacuum forming process;

 heat welding the inner door member to the outer door member.

16. A method in accordance with Claim 15 further comprising the step of locating a bracket assembly in the inner door member.

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17. A method in accordance with Claim 15 further comprising the step of injecting insulation foam into a chamber defined by the outer and inner door members.

18. A method in accordance with Claim 17 further comprising the step of drilling hinge pin holes in the outer door member and press fitting hinge pins into the outer door member.

19. A method in accordance with Claim 15 further comprising the steps of assembling a trigger and a handle to the mini door.

20. A mini door for a refreshment center of a refrigerator, the refrigerator having a fresh food door with an access opening therein, said mini door comprising an outer door member and an inner door member, said inner door member sized to partially extend through an access opening in said fresh food door.

21. A mini door in accordance with Claim 20 further comprising a handle secured to said outer door member and a trigger secured to said outer door member, said trigger comprising a grip, at least one leaf spring, and a pusher member.

22. A mini door in accordance with Claim 20 further comprising a bracket secured to said inner door member, a hinge arm secured to said bracket, and a stop member secured to said bracket and positioned to limit movement of said hinge arm.

23. A mini door in accordance with Claim 20 further comprising hinge pins secured to said outer door member.

24. A frame for a refreshment center of a refrigerator, the refrigerator having a fresh food door with an access opening therein, said frame comprising first and second spaced apart planar members and a keeper slot in said first member.

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25. A frame in accordance with Claim 24 further comprising a switch cavity for housing at least a portion of a switch assembly.

26. A light actuation system in a refreshment center in a fresh food compartment of a refrigerator, the refreshment center including a frame and a mini door secured to the frame by a hinge system, the hinge system including a slide which moves upward as the mini door is opened, said light actuation system comprising:

a switch comprising a switch arm, said switch being in electric circuit with a light in the fresh food compartment;

a switch actuator located over the slide so that as the slide moves upward, said switch actuator contacts said switch arm.

27. A light actuation system in accordance with Claim 26 wherein said switch actuator comprises an actuator block and an actuator arm, said actuator arm extending through a rib of the frame and over the slide.

28. A light actuation system in accordance with Claim 27 wherein when the mini door is opened, said actuator block rests on the rib.

29. A light actuation system in accordance with Claim 27 wherein when the mini door is closed, said actuator block engages and pushes against said switch arm.

30. A hinge system for a refreshment center of a refrigerator, the refreshment center including a mini door and a frame secured between outer and inner walls of a refrigerator door, said hinge system comprising:

brackets secured to the mini door;

hinge arms secured to the mini door bracket and to the frame;

and

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-25-

a stop member secured to said bracket and positioned to limit movement of at least one of said hinge arms.

31. A hinge system in accordance with Claim 30 further comprising a slide positioned between members of the frame, said
5 hinge arm secured to said slide.

32. A hinge system in accordance with Claim 30 further comprising hinge pins secured to the mini door and pivot slides secured to the frame, said pivot slides comprising bushings, and said hinge pins extending into respective bushings.

WO 99/01704

PCT/US98/13292

1/6

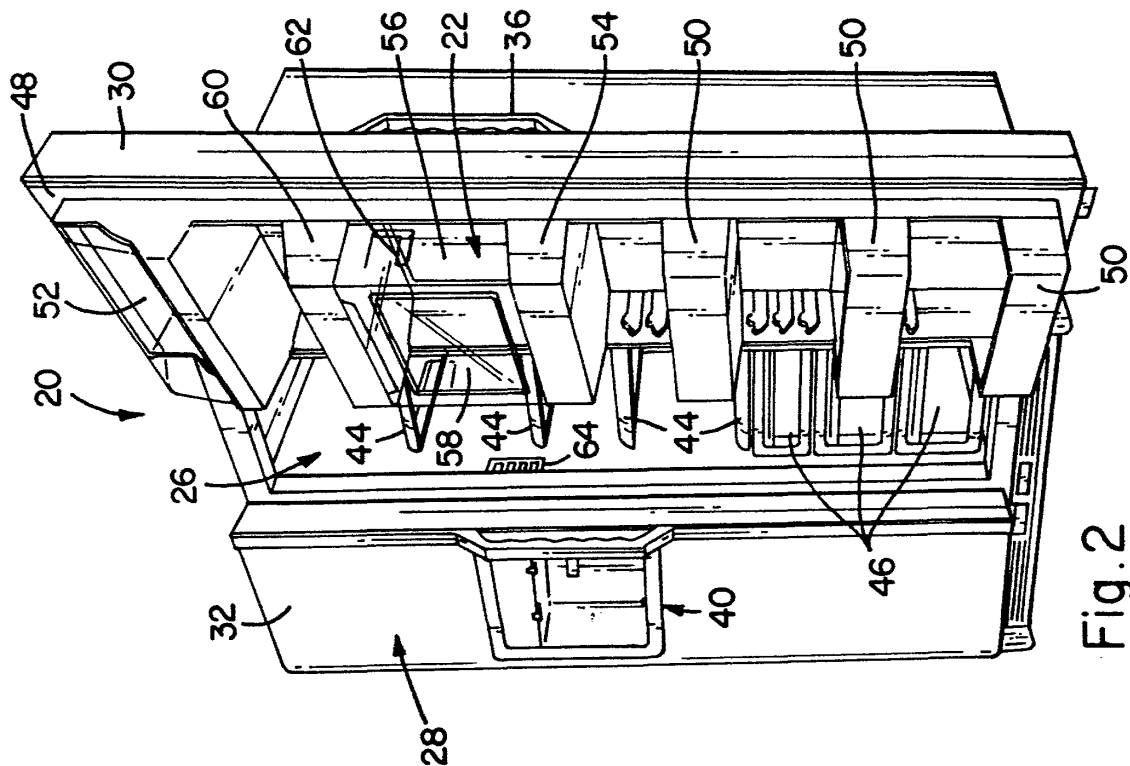


Fig. 2

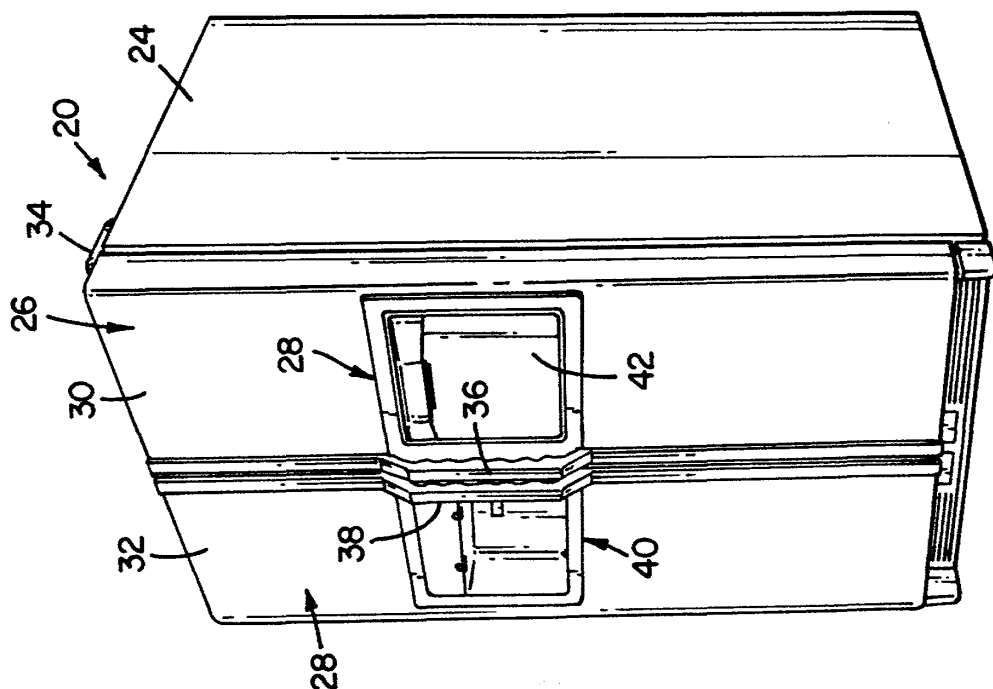


Fig. 1

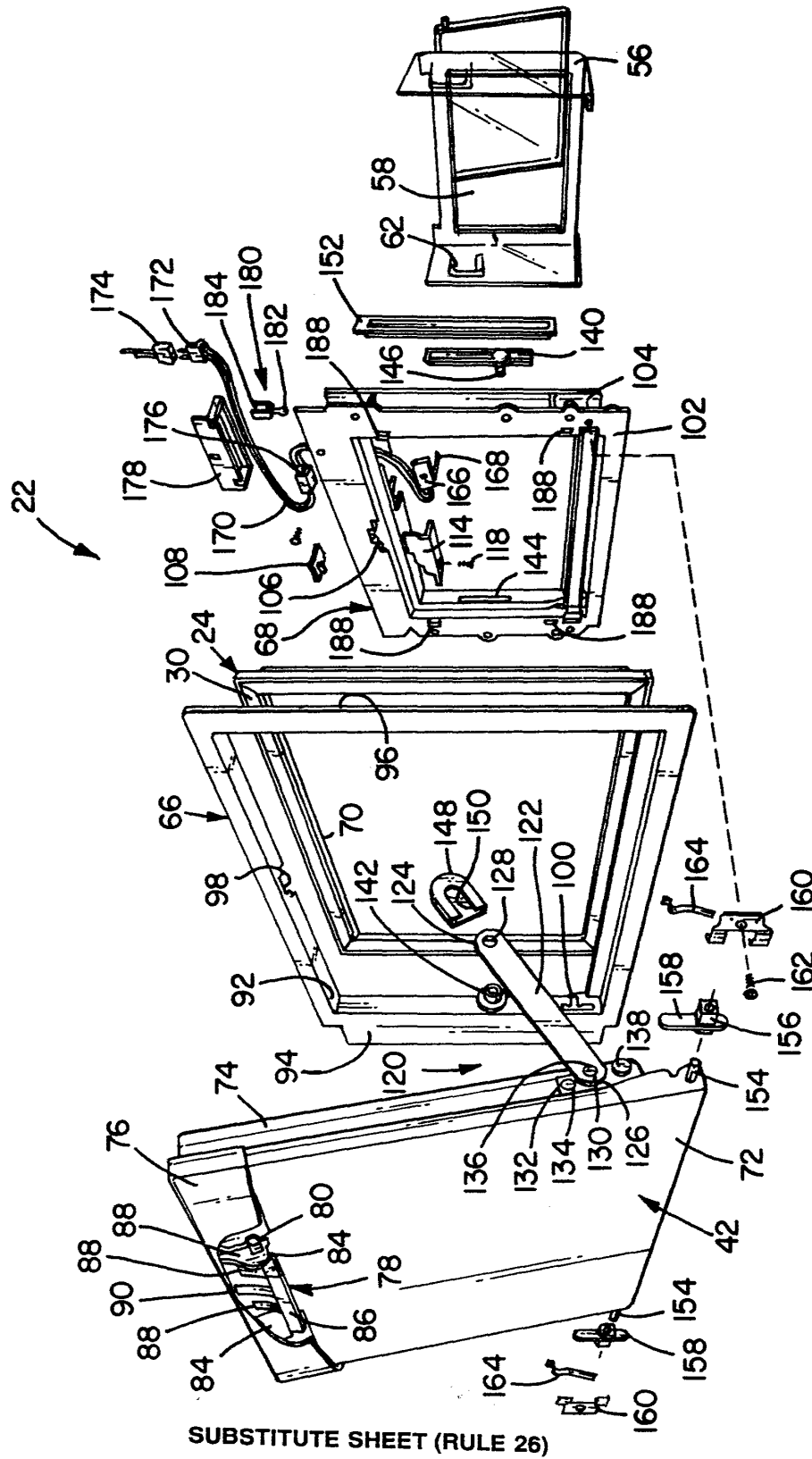


Fig. 3

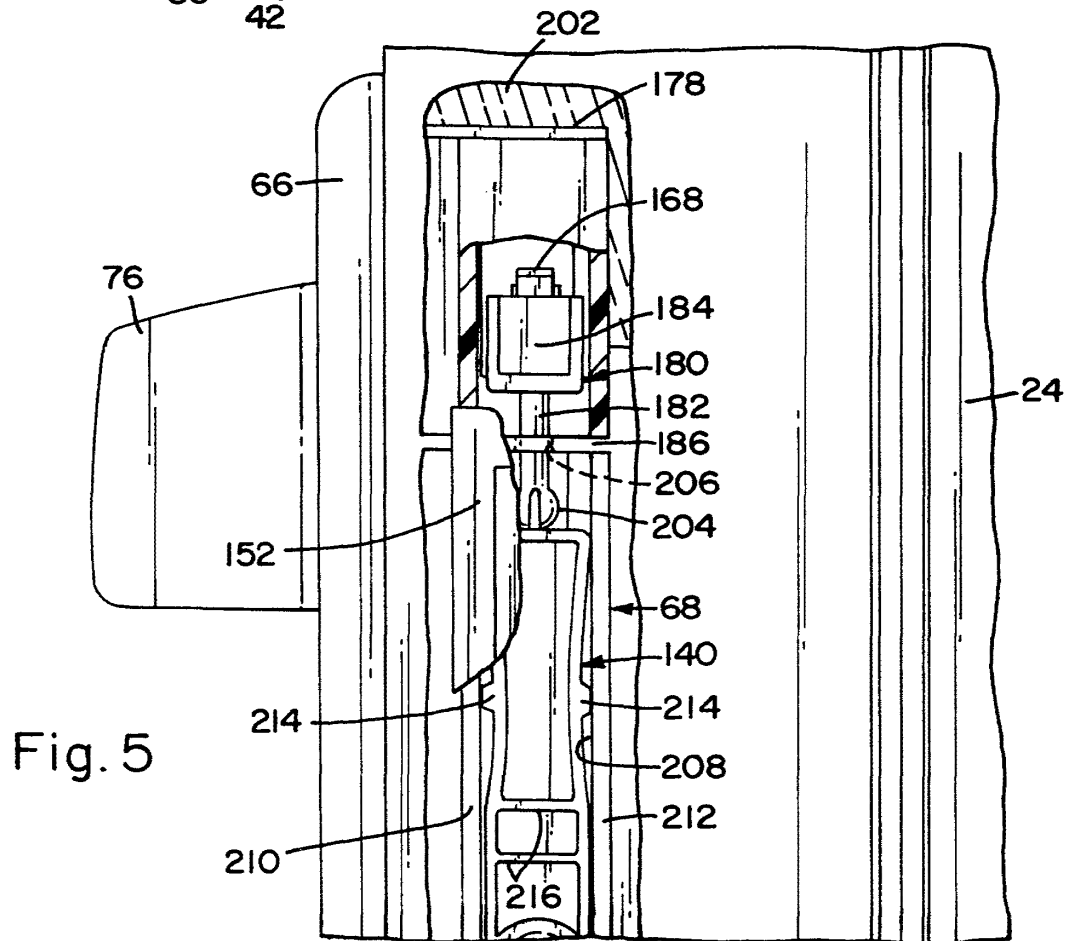
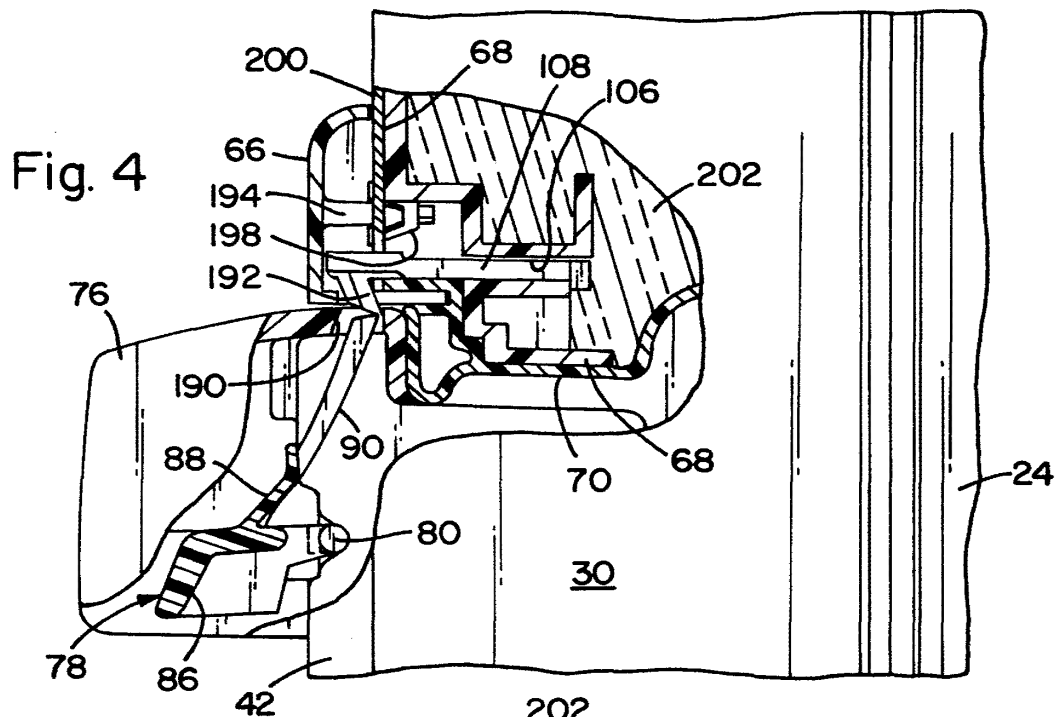
SUBSTITUTE SHEET (RULE 26)

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3/6



Page 310 of 1082
SUBSTITUTE SHEET (RULE 26)

Appx58597

WO 99/01704

4/6

PCT/US98/13292

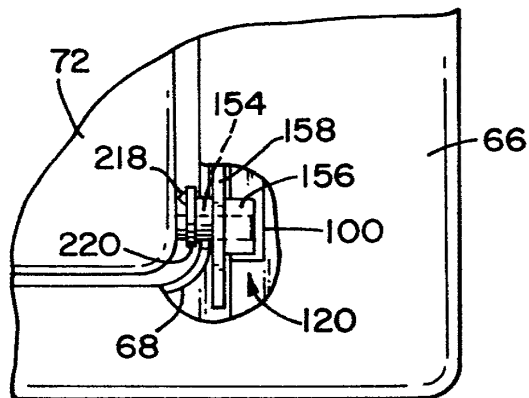


Fig. 6

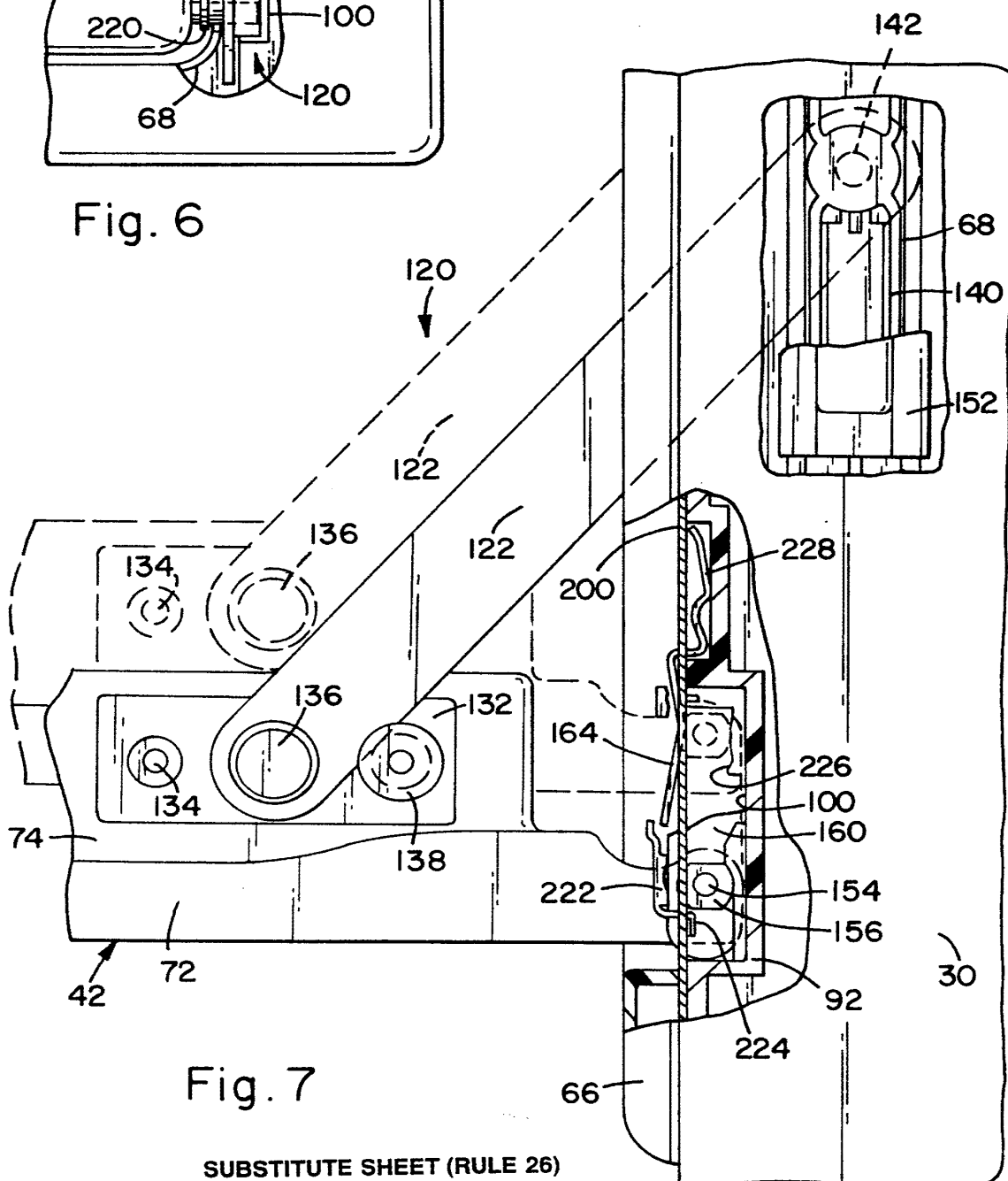


Fig. 7

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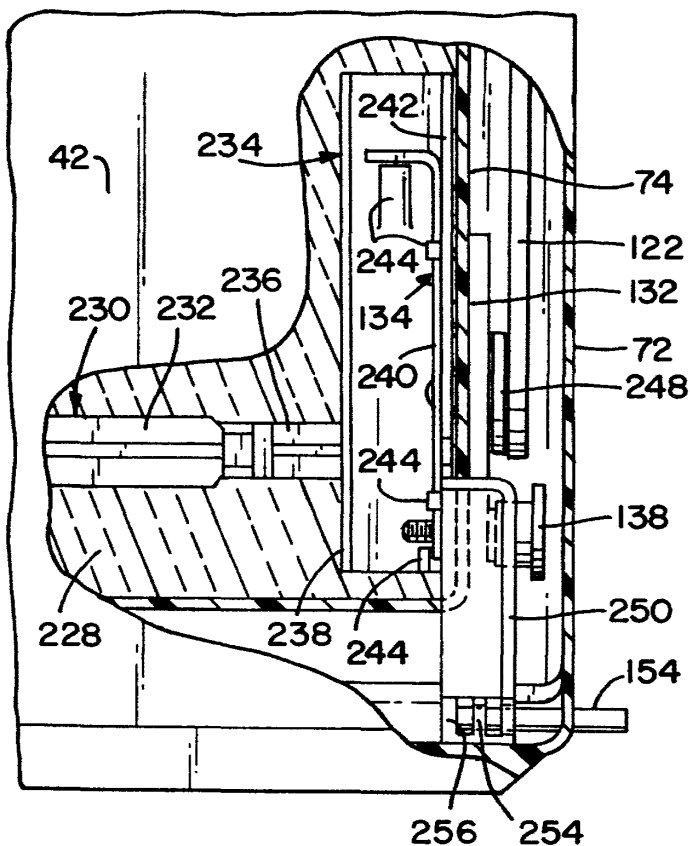


Fig. 8

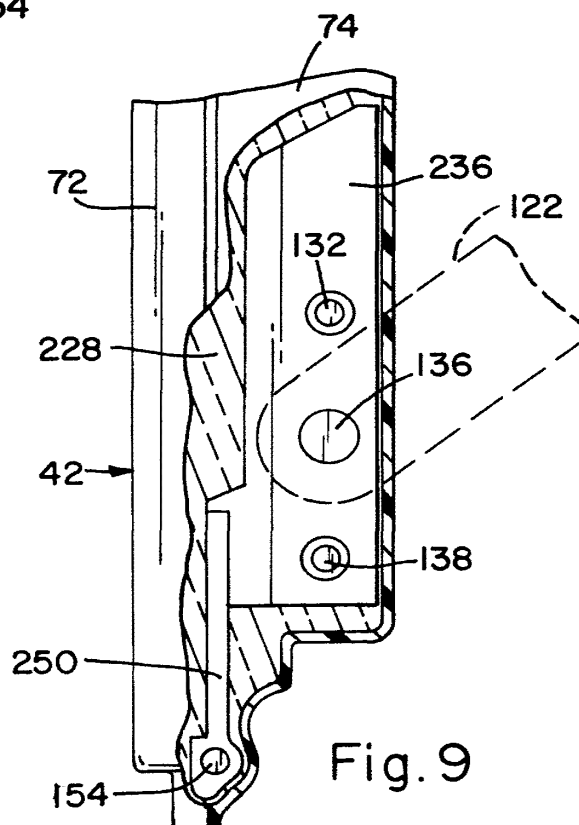


Fig. 9

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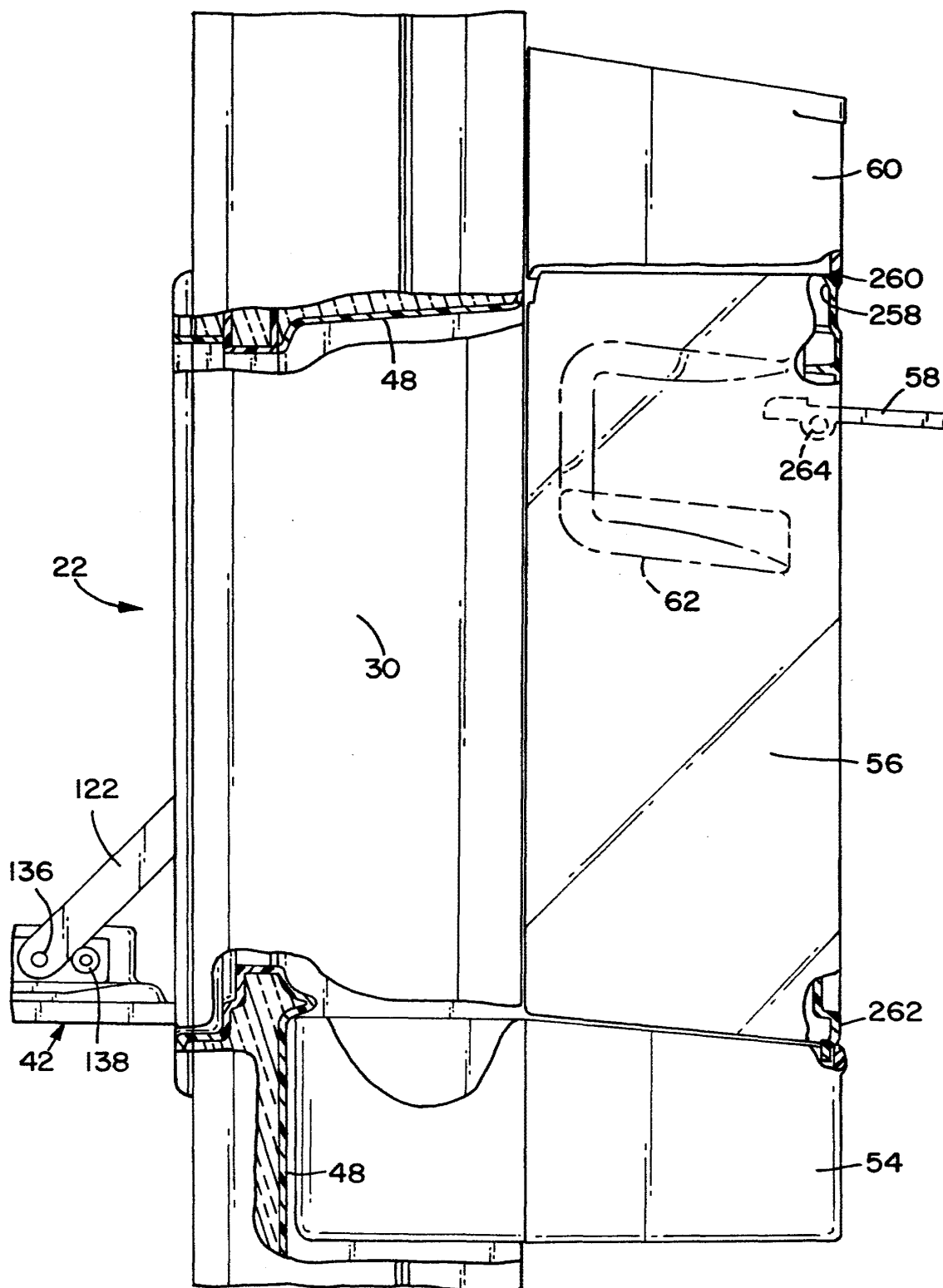


Fig. 10

SUBSTITUTE SHEET (RULE 26)

Page 322 of 1082

Appx58600

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	24459230
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Scott Cromar/Daniella Kellogg
Filer Authorized By:	Scott Cromar
Attorney Docket Number:	MASCER.002C1
Receipt Date:	28-DEC-2015
Filing Date:	01-JUL-2010
Time Stamp:	14:56:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		IDS_MASCER-002C1.pdf	53984 431f95092081cafd03ed7589d0390299116c844b	yes	4

CX-1622

	Multipart Description/PDF files in .zip description				
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Information:					
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CX-1622

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CX-1622

18	Foreign Reference	WO1999001704.pdf	1333410	no	33
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Information:					
Total Files Size (in bytes):				17166354	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Docket No.: MAS CER.002C1

Customer No. 64735

INFORMATION DISCLOSURE STATEMENT

Inventor	:	Jeroen Poeze
App. No.	:	12/829352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf. No.	:	8366

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted. Any foreign references may also include English abstract(s) and/or machine translation(s), but no representation is made as to their accuracy.

If the Examiner would like additional information regarding these references or if anything is unclear, the Examiner is invited to contact the undersigned for assistance.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed after the mailing date of a final action or after the mailing date of a Notice of Allowance. Please place these references in the file in accordance with 37 CFR 1.97(i).

Application No.: 12/829352
Filing Date: July 1, 2010

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 28, 2015

By: /Scott Cromar/ _____
Scott A. Cromar
Registration No. 65,066
Attorney of Record
Customer No. 64735
(949) 760-0404

22341586

12-28-15

C71622

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE**
Commissioner for Patents
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Alexandria, Virginia 22313-1450
 or **Fax** (571)-273-2885

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20995 7590 09/25/2015
KNOBBE MARTENS OLSON & BEAR LLP
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Scott Cromar	(Depositor's name)
Scott Cromar	(Signature)
2015-12-23	(Date)

01/08/2016 CCHAU2 00000002 111410 12829352
 01 FC:1501 960.00 DA

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	MASCER.002C1 -CERGA.002G+	8366

TITLE OF INVENTION: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/28/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIU, CHU CHUAN	3777	600-322000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
 (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. Knobbe, Martens,
 2. Olson & Bear LLP
 3. _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

MASIMO CORPORATION

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

IRVINE, CA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

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☐ Publication Fee (No small entity discount permitted)
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- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 11-1410 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature: /Scott Cromar/Date: 2015-12-23Typed or printed name: Scott CromarRegistration No. 65,066

Page 2 of 3

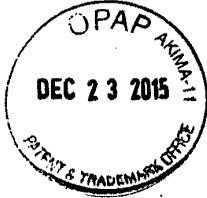
Knobbe Martens

INTELLECTUAL PROPERTY LAW

KNOBBE, MARTENS, OLSON & BEAR, LLP

2040 Main St., 14th Fl., Irvine, CA 92614
T (949) 760-0404

Scott A. Cromar
Scott.Cromar@knobbe.com



MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Attorney Docket No. : MASCER.002C1
Inventor(s) : Jeroen Poeze, et al.
For : MULTI-STREAM DATA COLLECTION SYSTEM FOR
NONINVASIVE MEASUREMENT OF BLOOD
CONSTITUENTS
Attorney : Scott A. Cromar
"Express Mail" Label No. : EV 971529793 US
Date of Deposit : December 23, 2015

I hereby certify that the accompanying

Issue Fee Transmittal; Comments on Examiner's Statement on Reasons for Allowance; Return
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37 CFR 1.10 on the date indicated above and are addressed to the Commissioner for Patents, P.O. Box 1450,
Alexandria, VA 22313-1450.

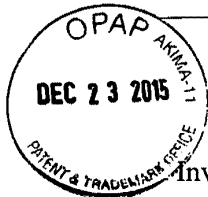

Ralph Auble

22345813

Docket No.: MASCER.002C1

PATENT

Please Direct All Correspondence to Customer Number 64735



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Jeroen Poeze
 App. No. : 12/829352
 Filed : July 10, 2010
 For : MULTI-STREAM DATA
 COLLECTION SYSTEM FOR
 NONINVASIVE MEASUREMENT OF
 BLOOD CONSTITUENTS
 Examiner : Liu, Chu Chuan
 Art Unit : 3777
 Conf. No. : 8366

CERTIFICATE OF MAILING

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December 23, 2015

(Date)

Scott A. Cromar,
Reg. No. 65,066

COMMENTS ON EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE**Mail Stop ISSUE FEE**

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Statement of Reasons for Allowance mailed on September 25, 2015, Applicant respectfully submits the following comments.

Applicant acknowledges the Examiner's statement regarding Allowable Subject Matter and agrees that the claimed subject matter is patentable. To the extent that there is any implication that the patentability of the claims rests on the recitation of a single feature, Applicant respectfully disagrees with the Examiner's Statement because it is the combination of features that makes the claims patentable. Accordingly, Applicant submits that the claims of the present application are allowable because each of the claims recites a combination of features that are not taught or suggested by the prior art. Applicant takes no other positions regarding the Allowable Subject Matter presented by the Examiner other than the positions Applicant may have previously taken during prosecution. Therefore, the Examiner's statement regarding

Docket No.: MAS CER.002C1
App. No.: 12/829352

December 23, 2015
Page 2 of 2

Allowable Subject Matter should not be attributed to Applicant as an indication of the basis for Applicant's belief that the claims are patentable. Furthermore, Applicant respectfully asserts that there may also be additional reasons for patentability of the claimed subject matter not explicitly stated in this record and Applicant does not waive rights to such arguments by not further addressing such reasons herein.

To the extent that there is any implication that the patentability of dependent claims is only attributable to the limitations in the independent claim from which each depends or that the dependent claims have the same scope as the claims from which they depend, Applicant respectfully disagrees and notes that it is each claim, taken as a whole, that is patentable. For dependent claims, their additional limitations may also provide additional reasons for patentability. Accordingly, Applicant submits that each of the allowed claims is allowable because the prior art does not teach or suggest the combination of features

Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the application's disclosure. Accordingly, reviewers of this or any child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers, disavowals, or abandonments of any subject matter supported by the present application, and any prior or alleged disclaimers, disavowals, or abandonments are hereby rescinded.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 23, 2015

By: /Scott Cromar/
Scott A. Cromar
Registration No. 65,066
Attorney of Record
Customer No. 64735
(949) 760-0404



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
12/829,352	07/01/2010	3777	1594	CERCA.002C1	22	3

CONFIRMATION NO. 8366

CORRECTED FILING RECEIPT



CC00000077884891

20995
 KNOBBE MARTENS OLSON & BEAR LLP
 2040 MAIN STREET
 FOURTEENTH FLOOR
 IRVINE, CA 92614

Date Mailed: 10/07/2015

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jeroen Poeze, Mission Viejo, CA;
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Applicant(s)

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 Ferdyan Lesmana, Irvine, CA;
 Massi Joe E. Kiani, Laguna Niguel, CA;

Power of Attorney: The patent practitioners associated with Customer Number 20995

Domestic Priority data as claimed by applicant

This application is a CON of 12/534,827 08/03/2009 ABN
 which claims benefit of 61/086,060 08/04/2008
 and claims benefit of 61/086,108 08/04/2008
 and claims benefit of 61/086,063 08/04/2008
 and claims benefit of 61/086,057 08/04/2008

page 1 of 4

and claims benefit of 61/091,732 08/25/2008
 This application 12/829,352
 is a CIP of 12/497,528 07/02/2009 PAT 8577431
 which claims benefit of 61/086,060 08/04/2008
 and claims benefit of 61/086,108 08/04/2008
 and claims benefit of 61/086,063 08/04/2008
 and claims benefit of 61/086,057 08/04/2008
 and claims benefit of 61/078,228 07/03/2008
 and claims benefit of 61/078,207 07/03/2008
 and claims benefit of 61/091,732 08/25/2008
 and is a CIP of 29/323,409 08/25/2008 PAT D621516
 and is a CIP of 29/323,408 08/25/2008 PAT D606659
 This application 12/829,352
 is a CIP of 12/497,523 07/02/2009 PAT 8437825
 which claims benefit of 61/086,060 08/04/2008
 and claims benefit of 61/086,108 08/04/2008
 and claims benefit of 61/086,063 08/04/2008
 and claims benefit of 61/086,057 08/04/2008
 and claims benefit of 61/078,228 07/03/2008
 and claims benefit of 61/078,207 07/03/2008
 and claims benefit of 61/091,732 08/25/2008
 and is a CIP of 29/323,409 08/25/2008 PAT D621516
 and is a CIP of 29/323,408 08/25/2008 PAT D606659

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 07/16/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/829,352**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

Preliminary Class

600

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international

page 2 of 4

application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national

security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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CX-1622



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	10/05/2015
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER
LIU, CHU CHUAN

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
10/05/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 12829352

Applicant : Poeze

Filing Date : 07/01/2010

Date Mailed : 10/05/2015

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The application is not in compliance with 37 CFR 1.78, as indicated in the attachment. The consequences of failure to respond within the above-identified time period are set forth in the attachment.

Even if the Office has recognized a benefit claim and has entered it into the Office's database and included it on applicant's filing receipt, the benefit claim is not a proper benefit claim unless the reference in compliance with 37 CFR 1.78 is included, depending upon the application's filing date and as indicated in the attachment, in an application data sheet or in the first sentence(s) of the specification and all other requirements are met.

See attachment.

*A copy of this notice **MUST** be returned with the reply. Please address response to
"Mail Stop Issue Fee, Commissioner for Patents,
P.O. Box 1450, Alexandria, VA 22313-1450".*

/Joseph Boris/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 12829352**APPLICATION FILED PRIOR TO SEPTEMBER 16, 2012,
NOT IN COMPLIANCE WITH 37 CFR 1.78**

- ☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification does not indicate the relationship (continuation, division, continuation-in-part) to the prior U.S. nonprovisional application or international application designating the U.S. See document coded dated , listing application number(s) .
- ☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title does not provide the U.S. nonprovisional application number (series code and serial number) or, with respect to an international PCT application designating the U.S., it provides the international application number or international filing date but not both. See document coded dated , in which the following is missing: .
- ☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. nonprovisional application number, international PCT application number, or international PCT filing date. See document coded dated , in which the following error was made: .
- ☐ The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title, thus removing the validating link under 35 U.S.C. 119(a)-(d) to a prior foreign application or under 35 U.S.C. 119(e) to a prior U.S. provisional application.
- ☐ The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title.
- ☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application is not present on an application data sheet or in first sentence(s) of the specification following the title.
- ☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title does not provide the provisional application number (series code and serial number). See document coded dated , in which the following is missing: .
- ☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. provisional application number. See document coded dated , in which the following error was made: .
- ☒ Other: The ADS 01/19/15 does not provide relationship for applications 29323408 and 29323409 in relation to 12497523.

HOW TO RESPOND

A proper response to this notice would include any one of: (1) a supplemental Application Data Sheet (ADS) pursuant to 37 CFR 1.76(c) which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); (2) an amendment to the first sentence(s) of the specification which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); or (3) a petition filed pursuant to the provisions of 37 CFR 1.78(a)(3) or 37 CFR 1.78(a)(6) if the benefit information from the document identified above by code and date does not accurately reflect the benefits under 35 U.S.C. 119(e), 120, 121 or 365(c) as claimed by applicant (a grantable petition would include either a supplemental ADS or an amendment to the first sentence(s) of the specification as required by 37 CFR 1.78(a)(3)(i) or 37 CFR 1.78(a)(6)(i)). Such amendments to the specification or supplemental ADS submission may be filed after payment of the issue fee if limited to informalities noted herein. See Waiver of 37 CFR 1.312 for Document Required by Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004).

WARNING: If Applicant fails to timely submit a proper response, the benefit information will be deleted and the patent will be printed without the benefit information present.

Docket No.: CERCA.002C1

October 5, 2015

Page 1 of 2

Please Direct All Correspondence to Customer Number 20995

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	: Jeroen Poeze
App. No.	: 12/829352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf. No.	: 8366

**RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS DATED
OCTOBER 5, 2015**

Mail Stop Issue Fee

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to Notice to File Corrected Application Papers dated October 5, 2015, enclosed are the following:

- (X) Copy of the Notice to File Corrected Application Papers dated October 5, 2015.
- (X) Supplemental Application Data Sheet.

The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment, to Account No. 11-1410.

CX-1622

Docket No.: CERCA.002C1
App. No.: 12/829352

October 5, 2015
Page 2 of 2

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2015-10-05_____

By: /Scott Cromar/_____

Scott A. Cromar
Registration No. 65,066
Attorney of Record
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(949) 760-0404

21751884

CX-1622



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

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IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
10/05/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
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Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 12829352
Applicant : Poeze
Filing Date : 07/01/2010
Date Mailed : 10/05/2015

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The application is not in compliance with 37 CFR 1.78, as indicated in the attachment. The consequences of failure to respond within the above-identified time period are set forth in the attachment.

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See attachment.

*A copy of this notice **MUST** be returned with the reply. Please address response to
"Mail Stop Issue Fee, Commissioner for Patents,
P.O. Box 1450, Alexandria, VA 22313-1450".*

/Joseph Boris/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 12829352**APPLICATION FILED PRIOR TO SEPTEMBER 16, 2012,
NOT IN COMPLIANCE WITH 37 CFR 1.78**

- ☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification does not indicate the relationship (continuation, division, continuation-in-part) to the prior U.S. nonprovisional application or international application designating the U.S. See document coded dated , listing application number(s) .
- ☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title does not provide the U.S. nonprovisional application number (series code and serial number) or, with respect to an international PCT application designating the U.S., it provides the international application number or international filing date but not both. See document coded dated , in which the following is missing: .
- ☐ The 37 CFR 1.78(a)(2) reference on the application data sheet or in the first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. nonprovisional application number, international PCT application number, or international PCT filing date. See document coded dated , in which the following error was made: .
- ☐ The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title, thus removing the validating link under 35 U.S.C. 119(a)-(d) to a prior foreign application or under 35 U.S.C. 119(e) to a prior U.S. provisional application.
- ☐ The 37 CFR 1.78(a)(2) reference to the prior U.S. nonprovisional application or international application designating the U.S. is not present on an application data sheet or in the first sentence(s) of the specification following the title.
- ☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application is not present on an application data sheet or in first sentence(s) of the specification following the title.
- ☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title does not provide the provisional application number (series code and serial number). See document coded dated , in which the following is missing: .
- ☐ The 37 CFR 1.78(a)(5) reference to the prior U.S. provisional application on an application data sheet or in first sentence(s) of the specification following the title shows an incorrect, incomplete, or illegible U.S. provisional application number. See document coded dated , in which the following error was made: .
- ☒ Other: The ADS 01/19/15 does not provide relationship for applications 29323408 and 29323409 in relation to 12497523.

HOW TO RESPOND

A proper response to this notice would include any one of: (1) a supplemental Application Data Sheet (ADS) pursuant to 37 CFR 1.76(c) which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); (2) an amendment to the first sentence(s) of the specification which provides benefit information that complies with 37 CFR 1.78(a)(2) or 37 CFR 1.78(a)(5); or (3) a petition filed pursuant to the provisions of 37 CFR 1.78(a)(3) or 37 CFR 1.78(a)(6) if the benefit information from the document identified above by code and date does not accurately reflect the benefits under 35 U.S.C. 119(e), 120, 121 or 365(c) as claimed by applicant (a grantable petition would include either a supplemental ADS or an amendment to the first sentence(s) of the specification as required by 37 CFR 1.78(a)(3)(i) or 37 CFR 1.78(a)(6)(i)). Such amendments to the specification or supplemental ADS submission may be filed after payment of the issue fee if limited to informalities noted herein. See Waiver of 37 CFR 1.312 for Document Required by Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004).

WARNING: If Applicant fails to timely submit a proper response, the benefit information will be deleted and the patent will be printed without the benefit information present.

SUPPLEMENTAL APPLICATION DATA SHEET**Application Information**

Application Number:: 12/829352
Filing Date:: July 1, 2010
Application Type:: Regular
Subject Matter:: Utility
Title:: MULTI-STREAM DATA COLLECTION SYSTEM FOR
NONINVASIVE MEASUREMENT OF BLOOD
CONSTITUENTS
Attorney Docket Number:: CERCA.002C1

Applicant 1 Information

Applicant Authority Type:: Inventor
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Family Name:: Poeze
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State or Prov. of Residence:: CA
Country of Residence:: US
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City:: Mission Viejo
State or Province:: CA
Country:: US
Postal or Zip Code:: 92692

Applicant 2 Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: BR
Status:: Full Capacity

1

Supplemental 12/829352 July 1, 2010 10/5/15

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Family Name:: Lamego
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State or Prov. of Residence:: CA
Country of Residence:: US
Street:: 10292 Orange Avenue
City:: Cupertino
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Applicant 3 Information

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State or Prov. of Residence:: CA
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City:: Lake Forest
State or Province:: CA
Country:: US
Postal or Zip Code:: 92630

Applicant 4 Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: BR
Status:: Full Capacity
Given Name:: Cristiano

2

Supplemental 12/829352 July 1, 2010 10/5/15

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Street:: 21622 Marguerite Pkwy, #6
City:: Mission Viejo
State or Province:: CA
Country:: US
Postal or Zip Code:: 92692

Applicant 5 Information

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Country of Residence:: US
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City:: Garden Grove
State or Province:: CA
Country:: US
Postal or Zip Code:: 92844

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Primary Citizenship Country:: NL
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Given Name:: Johannes
Family Name:: Bruinsma

City of Residence:: Mission Viejo
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Country of Residence:: US
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State or Province:: CA
Country:: US
Postal or Zip Code:: 92691

Applicant 7 Information

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Primary Citizenship Country:: ID
Status:: Full Capacity
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Family Name:: Lesmana
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State or Prov. of Residence:: CA
Country of Residence:: US
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City:: Irvine
State or Province:: CA
Country:: US
Postal or Zip Code:: 92602

Applicant 8 Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Full Capacity
Given Name:: Massi Joe
Middle Name:: E.
Family Name:: Kiani

4

Supplemental 12/829352 July 1, 2010 10/5/15

City of Residence:: Laguna Nigel
 State or Prov. of Residence:: CA
 Country of Residence:: US
 Street:: 35 Brindisi
 City:: Laguna Nigel
 State or Province:: CA
 Country:: US
 Postal or Zip Code:: 92677

Correspondence Information

Correspondence Customer Number:: 20995
 Phone Number:: (949) 760-0404
 Fax Number:: (949) 760-9502
 E-Mail Address:: efilings@knobbe.com

Representative Information

Representative Customer Number:: 20995

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	Continuation of	12/534827	2009-08-03
12/534827	non provisional of	61/086060	2008-08-04
12/534827	non provisional of	61/086108	2008-08-04
12/534827	non provisional of	61/086063	2008-08-04
12/534827	non provisional of	61/086057	2008-08-04
12/534827	non provisional of	61/091732	2008-08-25
This Application	Continuation in part of	12/497528	2009-07-02

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
12/497528	non provisional of	61/086060	2008-08-04
12/497528	non provisional of	61/086108	2008-08-04
12/497528	non provisional of	61/086063	2008-08-04
12/497528	non provisional of	61/086057	2008-08-04
12/497528	non provisional of	61/078228	2008-07-03
12/497528	non provisional of	61/078207	2008-07-03
12/497528	non provisional of	61/091732	2008-08-25
12/497528	Continuation in part of	29/323409	2008-08-25
12/497528	Continuation in part of	29/323408	2009-12-22 <u>2008-08-25</u>
This Application	Continuation in part of	12/497523	2009-07-02
12/497523	non provisional of	61/086060	2008-08-04
12/497523	non provisional of	61/086108	2008-08-04
12/497523	non provisional of	61/086063	2008-08-04
12/497523	non provisional of	61/086057	2008-08-04
12/497523	non provisional of	61/078228	2008-07-03
12/497523	non provisional of	61/078207	2008-07-03
12/497523	non provisional of	61/091732	2008-08-25
<u>12/497523</u>	<u>Continuation in part of</u>	<u>29/323409</u>	<u>2008-08-25</u>
<u>12/497523</u>	<u>Continuation in part of</u>	<u>29/323408</u>	<u>2008-08-25</u>

Foreign Priority Information

Country::	Application Number::	Filing Date::	Priority Claimed::
			No

Assignment Information

Assignee Name:: Cercacor Laboratories, Inc.
Street:: ~~30 Fairbanks, Suite 100~~ 189 Technology Drive
City:: Irvine
State or Province:: CA
Country:: US
Postal or Zip Code:: 92618

Dated: October 5, 2015

By: /Scott Cromar/_____
Scott A. Cromar
Registration No. 65,066
Attorney of Record
Customer No. 20995
(949) 760-0404

19773971

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	23694877
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Scott Cromar/Gustavo Lopez
Filer Authorized By:	Scott Cromar
Attorney Docket Number:	CERCA.002C1
Receipt Date:	05-OCT-2015
Filing Date:	01-JUL-2010
Time Stamp:	19:01:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Post Allowance Communication - Incoming	RESP_CORRECTED_APP_PAPER S_CERCA-002C1.pdf	155445 6c758fc2c2ed6ff2129d9f982fb8eab26d32c374	no	5

Warnings:**Information:**

CX-1622

2	Application Data Sheet	SUPP-ADS_CERCA-002C1.pdf	28791 091ed6160f8f58ead50b8d46cfe09167aec c643	no	7
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
Total Files Size (in bytes):			184236		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

20995 7590 09/25/2015
 KNOBBE MARTENS OLSON & BEAR LLP
 2040 MAIN STREET
 FOURTEENTH FLOOR
 IRVINE, CA 92614

EXAMINER

LIU, CHU CHUAN

ART UNIT

PAPER NUMBER

3777

DATE MAILED: 09/25/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

TITLE OF INVENTION: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/28/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or **Fax** **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20995 7590 09/25/2015

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

TITLE OF INVENTION: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/28/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIU, CHU CHUAN	3777	600-322000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	09/25/2015
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 FOURTEENTH FLOOR
 IRVINE, CA 92614

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

DATE MAILED: 09/25/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
 (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 12/829,352 Examiner CHU CHUAN (JJ) LIU	Applicant(s) POEZE ET AL. Art Unit 3777 AIA (First Inventor to File) Status No
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Remarks filed on 08/03/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-9 and 14-22. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
 a) ☐ All b) ☐ Some *c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____.	5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
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/CHU CHUAN (JJ) LIU/ Examiner, Art Unit 3777	/TSE CHEN/ Supervisory Patent Examiner, Art Unit 3777
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Application/Control Number: 12/829,352
Art Unit: 3777

Page 2

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Scott Cromar on 09/10/2015. Amendments were made to fix potential 35 USC 112 issues.

The application has been amended as follows:

Claim 1, line 19, "substantially" was deleted; in line 20, "a substantially" was replaced by -- an --; and in line 25, "substantially" was deleted.

Claim 14, line 15, "substantially" was deleted; in line 16, "a substantially" was replaced by -- an --; and in line 22, "substantially" was deleted.

2. The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or suggest *"a first heat insulating shell housing said optical source, said first heat insulating shell including: a top surface; a bottom surface opposite said top surface; a cavity extending from said top surface to said bottom surface, wherein said top surface includes a curved surface at a periphery of said*

Application/Control Number: 12/829,352

Page 3

Art Unit: 3777

cavity; a heat sink comprising heat conducting material and disposed at least partially within said cavity, said heat sink having an outer convex surface that aligns with said curved surface of said periphery of said top surface to form an uninterrupted top convex surface of said housing wherein heat produced by said optical source is dissipated via said heat sink through said cavity; and one or more curved fins that form said outer convex surface of said heat sink, wherein a thickness of said outer convex surface of said heat sink is less than a length of said top convex surface of said housing” in combination with the other claimed elements/steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Application/Control Number: 12/829,352
Art Unit: 3777

Page 4

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHU CHUAN (JJ) LIU/
Examiner, Art Unit 3777

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

Search Notes 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC- SEARCHED		
Symbol	Date	Examiner
A61B5/1455,14551,14532	03/24/2015	CCL
A61B5/1455,14551,14552,14532	09/10/2015	CCL

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	04/10/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	10/29/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	03/25/2014	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	09/09/2014	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	03/24/2015	CCL
356	41	03/24/2015	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	09/10/2015	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	04/10/2013	CCL

/CHU CHUAN (JJ) LIU/
Examiner.Art Unit 3777

SEARCH NOTES		
Search Notes	Date	Examiner
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	10/29/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	03/25/2014	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	09/09/2014	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT, CPC) See Search History	03/24/2015	CCL
Google NPL Search	03/24/2015	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT, CPC) See Search History	09/10/2015	CCL
Google NPL Search	09/10/2015	

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61B5	1455,14551,14552,14532	09/10/2015	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	09/10/2015	

/CHU CHUAN (JJ) LIU/
Examiner.Art Unit 3777

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L5	0	(convex) with fin\$1 same heat with dissipat\$3 same (level\$3 height) and (A61B5/1455,14551,14552,14532.cpc. 600/310-344,473,476.ccls. 356/41.ccls.)	US-PGPUB; USPAT	OR	ON	2015/09/10 14:39
L3	1	("D606659").PN.	US-PGPUB; USPAT	OR	OFF	2015/09/10 14:37
L2	6	("2011/0004082").URPN.	USPAT	OR	ON	2015/09/10 14:35
S131	1	("5792052").PN.	US-PGPUB; USPAT	OR	OFF	2015/09/08 10:31
S130	1	("5520177").PN.	US-PGPUB; USPAT	OR	OFF	2015/09/08 10:29
S129	27	(convex) with fin\$1 same heat with dissipat\$3 same (level\$3 height)	US-PGPUB; USPAT	OR	ON	2015/09/08 10:04
S128	18	(convex) with fin\$1 same heat with dissipat\$3 same (enclosure hous\$3)	US-PGPUB; USPAT	OR	ON	2015/09/08 10:01
S127	17	(convex) with fin\$1 same heat with sink same (enclosure hous\$3)	US-PGPUB; USPAT	OR	ON	2015/09/08 09:55
S126	0	(convex) with fin\$1 same heat with sink same (level\$3 height) same (enclosure hous\$3)	US-PGPUB; USPAT	OR	ON	2015/09/08 09:54
S125	6	(curved curvature) with fin\$1 same heat with sink same (level\$3 height) same (enclosure hous\$3)	US-PGPUB; USPAT	OR	ON	2015/09/08 09:53
S124	24	(curved curvature) with fin\$1 same heat with sink same surface same (level\$3 height)	US-PGPUB; USPAT	OR	ON	2015/09/08 09:45
S123	312	(curved curvature) with fin\$1 same heat with sink same surface	US-PGPUB; USPAT	OR	ON	2015/09/08 09:43
S122	2	S121 and accommodat\$3	US-PGPUB; USPAT	OR	ON	2015/09/08 09:41
S121	544	(curved curvature) with fin\$1 same heat with sink	US-PGPUB; USPAT	OR	ON	2015/09/08 09:39

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp

EAST Search History

CX-1622

L7	0	(convex) with fin\$1 same heat with dissipat\$3 and (A61B5/1455,14551,14552,14532.cpc. 600/310-344,473,476.ccls. 356/41.ccls.)	US-PGPUB; USPAT	OR	ON	2015/09/10 14:39
L6	0	(convex) with fin\$1 same heat with dissipat\$3 same (level\$3 height) and (A61B5/1455,14551,14552,14532.cpc. 600/310-344,473,476.ccls. 356/41.ccls.)	US-PGPUB; USPAT	OR	ON	2015/09/10 14:39
L4	20	heat adj sink with (curve\$1 arc) with fin\$1 and (A61B5/1455,14551,14552,14532.cpc. 600/310-344,473,476.ccls. 356/41.ccls.)	US-PGPUB; USPAT	OR	ON	2015/09/10 14:39

9/ 10/ 2015 2:40:08 PM**C:\ Users\ cliu\ Documents\ EAST\ Workspaces\ 12829352.wsp**



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BIB DATA SHEET

CONFIRMATION NO. 8366

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.	
12/829,352	07/01/2010	600	3777	CERCA.002C1	
APPLICANTS INVENTORS Jeroen Poeze, Mission Viejo, CA; Marcelo Lamego, Coto De Caza, CA; Sean Merritt, Lake Forest, CA; Cristiano Dalvi, Mission Viejo, CA; Hung Vo, Garden Grove, CA; Johannes Bruinsma, Mission Viejo, CA; Ferdyan Lesmana, Irvine, CA; Massi Joe E. Kiani, Laguna Niguel, CA;					
** CONTINUING DATA ***** This application is a CON of 12/534,827 08/03/2009 ABN which claims benefit of 61/086,108 08/04/2008 and claims benefit of 61/086,063 08/04/2008 and claims benefit of 61/086,057 08/04/2008 and claims benefit of 61/091,732 08/25/2008 This application 12/829,352 07/01/2010 is a CON of 12/497,528 07/02/2009 PAT 8577431 which claims benefit of 61/086,060 08/04/2008 and claims benefit of 61/086,108 08/04/2008 and claims benefit of 61/086,063 08/04/2008 and claims benefit of 61/086,057 08/04/2008 and claims benefit of 61/078,228 07/03/2008 and claims benefit of 61/078,207 07/03/2008 and claims benefit of 61/091,732 08/25/2008 and is a CIP of 29/323,409 08/25/2008 PAT D621516 and is a CIP of 29/323,408 08/25/2008 PAT D606659 This application 12/829,352 07/01/2010 is a CON of 12/497,523 07/02/2009 PAT 8437825 which claims benefit of 61/086,060 08/04/2008 and claims benefit of 61/086,108 08/04/2008 and claims benefit of 61/086,063 08/04/2008 and claims benefit of 61/086,057 08/04/2008 and claims benefit of 61/078,228 07/03/2008 and claims benefit of 61/078,207 07/03/2008 and claims benefit of 61/091,732 08/25/2008 and is a CIP of 29/323,409 08/25/2008 PAT D621516 and is a CIP of 29/323,408 08/25/2008 PAT D606659					
** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 07/16/2010					
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS

BIB (Rev. 05/07).

CX-1622

Issue Classification 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC						
Symbol					Type	Version
A61B		5		1455	F	2013-01-01
A61B		5		14532	I	2013-01-01
A61B		5		14546	I	2013-01-01
A61B		5		14552	I	2013-01-01
A61B		5		6816	I	2013-01-01
A61B		5		6826	I	2013-01-01
A61B		5		6829	I	2013-01-01
A61B		5		6838	I	2013-01-01
A61B		5		6843	I	2013-01-01
A61B		2562		0233	A	2013-01-01
A61B		2562		046	A	2013-01-01
A61B		2562		146	A	2013-01-01


CPC Combination Sets						
Symbol			Type	Set	Ranking	Version

/CHU CHUAN (JJ) LIU/ Examiner.Art Unit 3777 (Assistant Examiner)	09/10/2015 (Date)	Total Claims Allowed: 18	
/TSE CHEN/ Supervisory Patent Examiner.Art Unit 3777 (Primary Examiner)	09/21/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 17

U.S. Patent and Trademark Office

Part of Paper No. 20150910

CX-1622

Issue Classification 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777


US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION														
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED									
600		322				A	6	1	B	5 / 1455 (2006.01.01)										
CROSS REFERENCE(S)																				
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																			
600	310																			

/CHU CHUAN (JJ) LIU/ Examiner.Art Unit 3777 (Assistant Examiner)	09/10/2015 (Date)	Total Claims Allowed: 18	
/TSE CHEN/ Supervisory Patent Examiner.Art Unit 3777 (Primary Examiner)	09/21/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 17

U.S. Patent and Trademark Office

Part of Paper No. 20150910

CX-1622

Issue Classification 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	13	17												
2	2	14	18												
3	3	15	19												
4	4	16	20												
5	5	17	21												
6	6	18	22												
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	10														
	11														
	12														
	13														
10	14														
11	15														
12	16														

/CHU CHUAN (JJ) LIU/ Examiner.Art Unit 3777 (Assistant Examiner)	09/10/2015 (Date)	Total Claims Allowed: 18	
/TSE CHEN/ Supervisory Patent Examiner.Art Unit 3777 (Primary Examiner)	09/21/2015 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 17

U.S. Patent and Trademark Office

Part of Paper No. 20150910

CX-1622



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	08/06/2015
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
08/06/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	

All participants (applicant, applicant's representative, PTO personnel):

(1) Chu Chuan Liu. (3) John Grover.

(2) Tse Chen. (4) Scott Cromar.

Date of Interview: 28 July 2015.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☒ 101 ☐ 112 ☐ 102 ☒ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: Terasawa and Xiao.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

During the interview, 35 USC 101 rejection and potential amendments of claim 1 were discussed. The amendments of "heat insulating shell"; "a single low-profile heat sink forming a curved outer surface of the first heat insulating shell" and sensor configurations of Figs. 3A and 17 were discussed. Examiner suggested that the configurations/relationships of the shell, low-profile heat sink and the attached structures should be set forth in the claims. Examiner indicated that an updated search is required when the formal response has been filed.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHU CHUAN (JJ) LIU/ Examiner, Art Unit 3777	/TSE CHEN/ Supervisory Patent Examiner, Art Unit 3777
---	--

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	: Jeroen Poeze
App. No.	: 12/829352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf. No.	: 8366

RESPONSE TO OFFICE ACTION DATED APRIL 1, 2015

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the outstanding office action, please consider the following:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Summary of Interview begins on page 6 of this paper.

Remarks begin on page 8 of this paper.

Application No.: 12/829352
Filing Date: July 1, 2010

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:

an optical source configured to emit optical radiation onto said tissue at said measurement site;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;

a housing positioning said optical source and said at least one photodetector with respect to said measurement site, said housing forming a clip sensor and including:

a first heat insulating shell housing said optical source, said first heat insulating shell including:

a top surface;

a bottom surface opposite said top surface;

a cavity extending from said top surface to said bottom surface, wherein said top surface includes a curved surface at a periphery of said cavity;

a heat sink comprising heat conducting material and disposed at least partially within said cavity, said heat sink having an outer convex surface that substantially aligns with said curved surface of said periphery of said top surface to form a substantially uninterrupted top convex surface of said housing wherein heat produced by said optical source is dissipated via said heat sink through said cavity; and

one or more curved fins that form said outer convex surface of said heat sink, wherein a thickness of said outer convex surface of said heat sink is substantially less than a length of said top convex surface of said housing;

a second shell hinged to the first heat insulating shell and housing said photodetector;

a spring disposed between and urging together the shells; and

Application No.: 12/829352
Filing Date: July 1, 2010

~~a heat sink integrated as a single piece with the first shell of said housing;
the heat sink molded into a curved outer surface of the first shell and including
one or more curved fins; and~~

a thermistor operably associated with said housing and configured to
output a temperature signal responsive to a temperature of said measurement site.

2. **(Original)** The sensor of claim 1, wherein said tissue at said measurement site
comprises a digit of said patient.

3. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is
reusable.

4. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is
disposable.

5. **(Previously Presented)** The sensor of claim 1, comprising a cable connected to a
patient monitor configured to process the at least one signal stream and the temperature signal to
determine output values for one or more physiological parameters.

6. **(Original)** The sensor of claim 5, wherein one of the one or more physiological
parameters comprises total hemoglobin.

7. **(Original)** The sensor of claim 5, wherein the thermistor measures the temperature
of said measurement site to correct wavelength drift from said optical source after attenuation by
said tissue.

8. **(Original)** The sensor of claim 1, wherein the sensor comprises plurality of
photodetectors configured to detect the optical radiation from said optical source after attenuation
by said tissue of said patient and each output a respective signal stream responsive to said
detected optical radiation.

9. **(Original)** The sensor of claim 1, wherein said optical source is configured to emit
optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

10-13. **(Canceled)**

14. **(Currently Amended)** A signal processing system configured to produce a signal
responsive to light attenuated by tissue at a measurement site on a patient, the system comprising:
a noninvasive clip-type optical sensor including:

a housing including:

Application No.: 12/829352
Filing Date: July 1, 2010

a first heat insulating shell housing an optical source configured to emit optical radiation onto said tissue at said measurement site, said first heat insulating shell including: [[,]]

a top surface;

a bottom surface opposite said top surface;

a cavity extending from said top surface to said bottom surface, wherein said top surface includes a curved surface at a periphery of said cavity;

a heat sink comprising heat conducting material and disposed at least partially within said cavity, said heat sink having an outer convex surface that substantially aligns with said curved surface of said periphery of said top surface to form a substantially uninterrupted top convex surface of said housing wherein heat produced by said optical source is dissipated via said heat sink through said cavity; and

one or more curved fins that form said outer convex surface of said heat sink, wherein a thickness of said outer convex surface of said heat sink is substantially less than a length of said top convex surface of said housing; and

a second shell hinged to the first heat insulating shell and a spring disposed between and urging together the shells;

~~an optical source configured to emit optical radiation onto said tissue at said measurement site and housed in the first shell;~~

~~a heat sink integrated as a single piece with the first shell, the heat sink molded into a curved outer surface of the first shell and including one or more curved fins;~~

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation, the at least one photodetector housed in the second shell; and

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Filing Date: July 1, 2010

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site; a monitor configured to process the at least one signal stream and the temperature ~~sensor~~ signal to determine output values for one or more physiological parameters; and a cable connected to the monitor providing communication between said optical sensor and said monitor.

15. **(Original)** The system of claim 14, wherein said tissue at said measurement site comprises a digit of said patient.

16. **(Original)** The system of claim 14, wherein at least a portion of said sensor is reusable.

17. **(Original)** The system of claim 14, wherein at least a portion of said sensor is disposable.

18. **(Original)** The system of claim 14, wherein one of the one or more physiological parameters comprises total hemoglobin.

19. **(Original)** The system of claim 14, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

20. **(Original)** The system of claim 14, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

21. **(Original)** The system of claim 14, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

22. **(Previously Presented)** The system of claim 14, wherein said monitor comprises a handheld monitor.

Application No.: 12/829352
Filing Date: July 1, 2010

SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

A telephone interview was conducted on July 28, 2015 and attended by Examiners Chu Chuan Liu and Tse Chen, and Applicant's representatives John Grover and Scott Cromar.

Exhibits and/or Demonstrations

The application was discussed in referenced to various drawings, including Figures 3A and 17.

Identification of Claims Discussed

Claims 1-22.

Identification of Prior Art Discussed

The art of record, including U.S. Patent No. 5,957,840 to Terasawa et al., U.S. Patent No. 6,343,223 to Chin et al., and U.S. Patent Application Publication No. 2009/0129102 to Xiao et al.

Proposed Amendments

Certain proposed amendments to Claims 1 and 14 were discussed.

Principal Arguments and Other Matters

Applicant argued that the claims were patent eligible under 35 U.S.C. § 101. Further, Applicant argued that the claims were patentable over the cited references.

Results of Interview

Regarding the rejections under 35 U.S.C. § 101, it was agreed that Claims 14-22 are patent eligible, and the Examiners agreed to remove the rejection. Applicant reserves the right to pursue the previously pending claims and/or the subject matter of the previously pending claims in this or a continuation application.

Regarding the rejection under 35 U.S.C. § 103(a), it was agreed that amendments to Claims 1 and 14, along the lines of those made herein, would render the claims patentable over the art of record. While Applicant disagreed with the rejection, Applicant agreed to amend each

Application No.: 12/829352
Filing Date: July 1, 2010

of independent Claims 1 and 14 consistent with the discussion during the interview, so as to advance prosecution and distinguish the claims over the art of record. The Examiners indicated that an updated search would be necessary upon filing of the amended claims. In order to facilitate progress of the application according to the guidelines of compact prosecution, the Examiners said that they would call if the updated search would cause any further rejections. Further, Applicant reserves the right to pursue the previously pending claims and/or the subject matter of the previously pending claims in this or a continuation application, as it is believed that the previously pending claims are patentable over the art of record.

Application No.: 12/829352
Filing Date: July 1, 2010

REMARKS

Applicant thanks Examiners Liu and Chen for the interview summarized above (“the interview”). By way of summary, Claims 1-22 were pending in this application. In the present amendment, the Applicant has amended Claims 1 and 14, and canceled Claims 10-13 without prejudice or disclaimer of subject matter. Accordingly, Claims 1-9 and 14-22 remain pending for consideration.

The Claims are Patent Eligible under 35 U.S.C. § 101

Claims 10-22 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. According to the Office Action Claims 10-22 are directed to a judicial exception without significantly more. Specifically, the Office Action alleges that Claims 10-22 are directed to the abstract idea of “determining an indication of perfusion from temperature measurements and determining an output measurement value indicative of the analyte based on the detected streams of optical radiation” and “processing signal and temperature to determine output values for one or more physiological parameters.” Applicant respectfully traverses these rejections, the characterization of the pending claims, and each and every implicit and/or explicit potential for reliance on Official Notice. In particular, Applicant traverses the argument that the claims are directed to an abstract idea. Further, under any characterization of the abstract idea, the claims comply with 35 U.S.C. § 101 at least because they recite “significantly more” than the alleged abstract idea.

Applicant notes that Claims 10-13 have been canceled, rendering the rejection of these claims under 35 U.S.C. § 101 moot. However, Applicant maintains that previously pending Claims 10-13, as well as previously pending Claims 1 and 14 (and their respective dependent claims) are patent eligible under 35 U.S.C. § 101, and reserves the right to pursue the previously pending claims and/or the subject matter of the previously pending claims in this or a continuation application.

Further, it was agreed during the interview that claims 14-22 are patent eligible under 35 U.S.C. § 101. Accordingly, Applicant requests withdrawal of the rejections of Claims 10-22 under 35 U.S.C. § 101.

Application No.: 12/829352
Filing Date: July 1, 2010

The Claims are Patentable over the Cited References

Claims 1-5, 8, 10-11, 14-17, and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,957,840 to Terasawa et al. (“Terasawa”) in view of U.S. Patent No. 6,343,223 to Chin et al. (“Chin”), and further in view of U.S. Patent Application Publication No. 2009/0129102 to Xiao et al. (“Xiao”); Claims 7, 12, and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Terasawa, Chin, and Xiao, and further in view of U.S. Patent No. 5,362,966 to Rosenthal (“Rosenthal”); Claims 9 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Terasawa, Chin, and Xiao, and further in view of U.S. Patent No. 6,606,509 to Schmitt (“Schmitt”); and Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Terasawa, Chin, and Xiao, and further in view of U.S. Patent Publication No. 2006/0220881 to Al-Ali (“Al-Ali”). Applicant respectfully traverses these rejections, the characterization of the pending claims, and each and every implicit and/or explicit potential for reliance on Official Notice. However, in view the agreement at the interview, the foregoing amendments, and for at least the reasons set forth below, Applicant respectfully disagrees and requests reconsideration of the aforementioned claims.

Initially, Applicant notes that Claims 10-13 have been canceled, rendering the rejection of these claims under 35 U.S.C. § 103(a) moot. However, Applicant maintains that previously pending Claims 10-13 are patentable under 35 U.S.C. § 103(a), and reserves the right to pursue the previously pending claims and/or the subject matter of the previously pending claims in this or a continuation application.

While each of Claims 1 and 14 varies in scope from one another, each has been amended to include similar features, as recited above. These amendments are made consistent with the discussion during the interview, as summarized above. As agreed during the interview, any combination of the cited references fails to teach or suggest each and every recitation of the claims. Accordingly, Applicant requests the 35 U.S.C. § 103(a) rejections of Claims 1 and 14 be withdrawn.

Applicant additionally requests the 35 U.S.C. § 103(a) rejections of each of the dependent claims be withdrawn at least for reasons similar to those discussed above with respect to Claims 1 and 14, and for the unique patentable features recited by each.

Application No.: 12/829352
Filing Date: July 1, 2010

Applicant maintains that previously pending Claims 1 and 14 (and their respective dependent claims) are patentable under 35 U.S.C. § 103(a), and reserves the right to pursue the previously pending claims and/or the subject matter of the previously pending claims in this or a continuation application.

Conclusion

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicant's undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicant's attorney can be reached at (949) 721-2812 or at the number listed below.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
CERCA.006C1	14/069974	NOISE SHIELDING FOR A NONINVAISE DEVICE	11/01/2013

Application No.: 12/829352
Filing Date: July 1, 2010

Docket No.	Serial No.	Title	Filed
CERCA.007C1	13/888266	CONTOURED PROTRUSION FOR IMPROVING SPECTROSCOPIC MEASUREMENT OF BLOOD CONSTITUENTS	05/06/2013
CERCA.008C1	14/227230	EMITTER DRIVER FOR NONINVASIVE PATIENT MONITOR	03/27/2014

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 3, 2015

By: /Scott Cromar/_____
Scott A. Cromar
Registration No. 65,066
Attorney of Record
Customer No. 20995
(949) 760-0404

20346767

Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Scott Cromar/Daniella Kellogg			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 1 month with \$0 paid	1251	1	200	200
Miscellaneous:				
Total in USD (\$)				200

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	23101084
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Scott Cromar/Kevin Kraus
Filer Authorized By:	Scott Cromar
Attorney Docket Number:	CERCA.002C1
Receipt Date:	03-AUG-2015
Filing Date:	01-JUL-2010
Time Stamp:	18:04:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$200
RAM confirmation Number	5154
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

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Appx58664

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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		RESP_CERCA-002C1.pdf	57294 c845a21b2f7c4de9f1a5f03083d9155d5fe613ea	yes	11
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	5	
	Applicant summary of interview with examiner		6	7	
	Applicant Arguments/Remarks Made in an Amendment		8	11	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30817 d490e8c575cd6fc84047bbe38db3544c4f2e4200	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			88111		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

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PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		<input type="checkbox"/> To be Mailed	
Substitute for Form PTO-875				12/829,352		07/01/2010			
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL					
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	08/03/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 18	Minus	** 22	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		0			
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE					
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.									
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".									
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									
LIE /ANTJUAN RIVERA/									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CX-1622



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	04/01/2015
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
04/01/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Office Action Summary	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 01/19/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-22 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-22 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 01/19/2015

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____

4) ☐ Other: ____

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DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. Applicant's amendments and remarks filed on 1/19/2015 have been fully considered.
3. Claims 1-22 are pending for examination.
4. According to the newly available guidance of the USPTO's 2014 Interim Eligibility Guidance", issued on December 16, 2014, 79 FR 74618 and "*Preliminary Examination Instructions in view of the Supreme Court Decision in Alice Corporation Pty. Ltd. v. CLS Bank International, et al*, No 13-298 (June 19, 2014)", a non-final rejection is made in order to determine the subject matter eligibility under 35 U.S.C. 101 of claims involving abstract ideas in view of this decision.

Claim Rejections - 35 USC § 101 – Abstract Idea

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 10-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

Claims 10 and 14 are directed to a method and a system for measuring an analyte and a temperature at a measurement site of a living patient and processing

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signal and temperature to determine output values for one or more physiological parameters. In this case, the claimed invention relies upon “determining an indication of perfusion from temperature measurements and determining an output measurement value indicative of the analyte based on the detected streams of optical radiation” and “processing signal and temperature to determine output values for one or more physiological parameters”, which are considered an abstract ideas, or a concept similar to those found by the courts to be abstract, as it involves mathematically relating data (prong 1 of the two-part test). With regards to the additional steps appended to the abstract idea (prong 2 of the two-part test), these steps/elements amount to no more than: insignificant post-solution activity and/or data gathering (e.g. a clip-type optical sensor; optical source, heat sink, photodetector, thermistor...etc); routine and conventional data processing steps (e.g. determining an indication of perfusion from temperature measurements and determining an output measurement value indicative of the analyte based on the detected streams of optical radiation; processing signal and temperature to determine output values for one or more physiological parameters); conventional elements of a computing environment (e.g. signal processor and monitor,); and/or applying the abstract idea in a computer environment according to well-known, routine, and conventional techniques (e.g. determining an indication of perfusion from temperature measurements and determining an output measurement value indicative of the analyte based on the detected streams of optical radiation; processing signal and temperature to determine output values for one or more physiological parameters). As discussed in *Mayo*, simply appending conventional steps, specified at a high level of

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generality,” to a method already “well known in the art” is not “enough” to supply the “inventive concept” needed to transform the abstract idea into a patent-eligible invention.

Additionally, the claims fail to recite any limitations that purport to improve the functioning of the computer itself or effect an improvement in any other technology or technical field, or provide meaningful limitations beyond generally linking the use of an abstract idea to a particular technological environment. While it is noted that the claim(s) result in determining an indication of perfusion and an output measurement value indicative of the analyte based on the detected streams of optical radiation; and determine output values for one or more physiological parameters, they are not considered a meaningful limitation beyond generally linking the use of an abstract idea to a particular technological environment.

Viewed as a whole, these additional claim element(s) do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea such that the claim(s) amounts to significantly more than the abstract idea itself.

For additional guidance, applicant is directed generally to MPEP 2106, the USPTO’s 2014 Interim Eligibility Guidance”, issued on December 16, 2014, 79 FR 74618, and the USPTO’s June 2014 Preliminary Examination Instructions in view of Alice v. CLS Bank, published online at: http://www.uspto.gov/patents/announce/interim_alice_guidance.jsp. This two-part analysis supersedes MPEP 2106(II)(A) and 2106(II)(B). Applicant should note that if the

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claimed invention reads on both eligible and non-eligible subject matter, a rejection under 35 U.S.C. 101 is necessitated over the non-eligible subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5, 8, 10-11, 14-17, and 20 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Terasawa et al. (USPN 5,957,840 – applicant cited) in view of Chin et al. (USPN 6,343,223 – applicant cited) and further in view of Xiao et al. (USPGPUB 2009/0129102). In regard to claim 1, Terasawa discloses a non-invasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Fig. 4 and associated descriptions; Col 1 lines 12-57), the sensor comprising: an optical source (element 5, Fig. 4 and Col 1 lines 12-57) configured to emit optical radiation onto said tissue at said measurement site (Fig. 4); at least one photodetector (element 6, Fig. 4) configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (Fig. 4) and output at least one respective signal stream responsive to said detected optical radiation (Col 1 lines 12-57); a housing (elements 1 and 2, Fig. 4 and associated descriptions) positioning said optical source and said at least one photodetector with

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respect to said measurement site (Fig. 4), said housing forming a clip sensor (Fig. 4) and including: a first shell (element 1, Fig. 4) housing said optical source; a second shell (element 2, Fig. 4) hinged to the first shell (element 3, Fig. 4) and housing said photodetector (Fig. 4); a spring disposed between and urging together the shells (element 4, Fig. 4). Terasawa does not specifically disclose a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site. Chin teaches a thermistor (element 60, Fig. 1 and associated descriptions) operably associated with said housing (element 15, Fig. 1) and configured to output a temperature signal responsive to a temperature of said measurement site (element 60, Fig. 1 and associated descriptions; Col 2 lines 36-58; Claim 1). Chin also teaches that the use of a thermistor will strengthen the pulse oximetry signals and increase the accuracy (Col 2 lines 59-64). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Terasawa) to incorporate the thermistor (Chin) in order to obtain more accuracy optical measurements. Terasawa as modified by Chin does not specifically disclose a heat sink integrated as a single piece with the first shell of said housing, the heat sink molded into a curved outer surface of the first shell and including one or more curved fins. Xiao teaches heat dissipating structure comprises a heat sink (element 100, Figs. 1 and 2 and [0014-0020]) integrated as a single piece (Figs. 1 and 2) with a housing (element 10, Figs. 1 and 2 and [0014-0020]) which encloses a LED module (element 200, Fig. 2 and [0014-0020]), the heat sink integrated into a curved outer surface of housing (Figs. 1 and 2 and [0018]) and including one or more curved

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fins (fins 20, Figs. 1 and 2 and [0018]). It is a common knowledge that the light source(s) utilized in pulse oximeter will generate heat and a heat sink(s) can be utilized to dispensing heat generated by light emitting sources to maintain the operating temperature as evidenced by Aronow (USPN 5,851,178 - cited in previous action). Also, molding process is commonly known in the art to integrate heat sink fins onto a surface as evidenced by Wang et al. (USPGPUB 2006/0005944). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Terasawa as modified by Chin) to incorporate the heat sink (Xiao) on the first shell, since one ordinary would have recognized that the use of heat sink can dispense heat generated from the light source. The rationale would have been more efficiently maintain the operating temperature of the light source.

In regard to claim 2, Terasawa as modified by Chin and Xiao discloses said tissue at said measurement site comprises a digit of said patient (Fig. 4 and Col 1 lines 5-10 of Terasawa; Col 5 lines 54-57 of Chin).

In regard to claim 3, Terasawa as modified by Chin and Xiao discloses at least a portion of said housing is reusable (Col 5 lines 54-57 of Chin).

In regard to claim 4, Terasawa as modified by Chin and Xiao discloses at least a portion of said housing is disposable (Col 5 lines 54-57 of Chin).

In regard to claim 5, Terasawa as modified by Chin and Xiao discloses a cable (Figs. 1 and 11 and associated descriptions of Chin) connected to a patient monitor (Fig. 1 and associated descriptions of Chin) configured to process the at least one

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signal stream and the temperature signal to determine output values for one or more physiological parameters (Figs. 1 and 11 and associated descriptions of Chin).

In regard to claim 8, Terasawa as modified by Chin and Xiao discloses the sensor comprises a plurality of photodetectors (Col 1 lines 29-39 of Chin) configured to detect the optical radiation from said optical source (Fig. 4 and associated descriptions of Terasawa; Fig. 1 and associated descriptions of Chin) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 4 and associated descriptions of Terasawa; Fig. 1 and associated descriptions of Chin).

In regard to claim 10, Terasawa as modified by Chin and Xiao discloses a method of measuring an analyte and a temperature at a measurement site of a living patient (referring to claim 1 above), said method comprising: emitting optical radiation on the measurement site from a first shell of a clip-type sensor (referring to claim 1 above); detecting said optical radiation after attenuation by tissue at the measurement site in a second shell of the clip-type sensor (referring to claim 1 above), the first shell hinged to the second shell (referring to claim 1 above); dissipating heat from the first shell using a heat sink integrated as a single piece with the first shell (referring to claim 1 above), the heat sink molded into a curved outer surface of the first shell and including one or more curved fins (referring to claim 1 above); measuring the temperature of said measurement site (referring to claim 1 above); using a signal processor (Fig. 1 and associated descriptions of Chin), determining an indication of perfusion from said temperature measurement (perfusion, abstract; Col 2 lines 47-64; Col 5 lines 12-20 of

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Chin); and determining an output measurement value indicative of the analyte based on the detected streams of optical radiation (oximeter, title; Fig. 1 and associated descriptions and Col 8 lines 50-62 of Chin).

In regard to claim 11, Terasawa as modified by Chin and Xiao discloses said tissue at said measurement site comprises a digit of said patient (Fig. 4 and Col 1 lines 5-10 of Terasawa; Col 5 lines 54-57 of Chin).

In regard to claim 14, Terasawa as modified by Chin and Xiao discloses a signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (referring to claim 1 above), the system comprising: a noninvasive optical clip type sensor (referring to claim 1 above) including: a housing forming a clip sensor (referring to claim 1 above) and including: a first shell housing an optical source (referring to claim 1 above); a second shell hinged to the first shell and housing said photodetector (referring to claim 1 above); a heat sink integrated with and forming part of the first shell, the heat sink molded into a curved outer surface of the first shell and including one or more curved fins (referring to claim 1 above); a spring disposed between and urging together the shells (referring to claim 1 above); an optical source configured to emit optical radiation onto said tissue at said measurement site (referring to claim 1 above); at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (referring to claim 1 above) and output at least one respective signal stream responsive to said detected optical radiation (referring to claims 1 and 10 above); a thermistor operably associated with said housing and configured to output a temperature signal

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responsive to a temperature of said measurement site (referring to claim 1 above); a monitor (Fig. 1 and associated descriptions of Chin) configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters (Fig. 1 and associated descriptions of Chin); and a cable connected to the monitor providing communication between said optical sensor and said monitor (Figs. 1, 2 and 11 and associated descriptions of Chin).

In regard to claim 15, Terasawa as modified by Chin and Xiao discloses said tissue at said measurement site comprises a digit of said patient (Fig. 4 and Col 1 lines 5-10 of Terasawa; Col 5 lines 54-57 of Chin).

In regard to claim 16, Terasawa as modified by Chin and Xiao discloses at least a portion of said sensor is reusable (Col 5 lines 54-57 of Chin).

In regard to claim 17, Terasawa as modified by Chin and Xiao discloses at least a portion of said sensor is disposable (Col 5 lines 54-57 of Chin).

In regard to claim 20, Terasawa as modified by Chin and Xiao discloses the sensor comprises a plurality of photodetectors (Col 1 lines 29-39 of Chin) configured to detect the optical radiation from said optical source (Fig. 4 and associated descriptions of Terasawa; Fig. 1 and associated descriptions of Chin) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 4 and associated descriptions of Terasawa; Fig. 1 and associated descriptions of Chin).

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4. Claims 6, 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Terasawa, Chin and Xiao as applied to claims 1, 5, 10, and 14 above, and further in view of Aronow. In regard to claims 6 and 13, Terasawa as modified by Chin and Xiao discloses all the claimed limitations except one of the one or more physiological parameters comprises total hemoglobin. Aronow teaches the optical monitoring system comprises light source(s) and photodetector(s) can be used to measure physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow). Total hemoglobin is also an important physiological parameter of a patient. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modified the sensor and the method (Terasawa as modified by Chin and Xiao) to incorporate measuring total hemoglobin (Aronow) in order to obtain more physiological information of the patient.

9. Claims 7, 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Terasawa, Chin and Xiao as applied to claims 1, 5, 10, and 14 above, and further in view of Rosenthal (USPN 5,362,966 - cited in previous action). In regard to claims 7, 12 and 19, Terasawa as modified by Chin and Xiao discloses all the claimed limitations except the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue. Rosenthal teaches the finger temperature of a measurement site is utilized to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal). Rosenthal also teaches the shift in peak

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wavelength will cause interferences of the optical measurements (Col 1 lines 26-63 of Rosenthal). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor, method and system (Terasawa as modified by Chin and Xiao) to incorporate wavelength drift correction method (Rosenthal) in order to obtain more accurate optical measurements.

10. Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Terasawa, Chin and Xiao as applied to claims 1 and 14 above, and further in view of Schmitt (USPN 6,606,509 – cited in previous action). In regard to claims 9 and 21, Terasawa as modified by Chin and Xiao discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Terasawa as modified by Chin and Xiao) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/ hydration information.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Terasawa, Chin and Xiao as applied to claim 14 above, and further in view of Al-Ali et al. (USPGPUB 2006/0220881 – cited in previous action). In regard to

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claim 22, Terasawa as modified by Chin and Xiao discloses all the claimed limitations except said monitor comprises handheld monitor. Al-Ali teaches a handheld monitor (abstract; Figs. 2, 7 and 11A) configured to be connected to a clip style sensor ([0040]) for displaying physiological parameters. Terasawa as modified by Chin and Xiao discloses a monitor (Fig. 1 of Chin) without a display. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the system (Rosenthal as modified by Schulz, Sakai, and Blank) to incorporate a handheld monitor (Al-Ali) in order to increase the portability of the system and display the results of measurements.

Response to Arguments

5. Applicant's amendment and argument with respect to claims 1-22 filed on 01/19/2015 have been fully considered but they are deemed to be moot in views of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHU CHUAN (JJ) LIU/
Examiner, Art Unit 3777

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

Notice of References Cited	Application/Control No. 12/829,352	Applicant(s)/Patent Under Reexamination POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2009/0129102	05-2009	XIAO et al.	362/373
*	B	US-2006/0005944	01-2006	Wang et al.	165/080.3
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS


*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47				
CLAIM		DATE								
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	21	✓	✓	✓	✓	✓	✓			
	22	✓	✓	✓	✓	✓	✓			

Search Notes 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC- SEARCHED		
Symbol	Date	Examiner
A61B5/1455,14551,14532	03/24/2015	CCL

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	04/10/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	10/29/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	03/25/2014	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	09/09/2014	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	03/24/2015	CCL
356	41	03/24/2015	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	04/10/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	10/29/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	03/25/2014	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	09/09/2014	CCL

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SEARCH NOTES		
Search Notes	Date	Examiner
Updated EAST Search (TEXT, USPGPUB, USPAT, CPC) See Search History	03/24/2015	CCL
Google NPL Search	03/24/2015	CCL

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L59	629	molded and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2015/03/24 13:28
L58	200	perfusion with temperature and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2015/03/24 12:31
L57	6	perfusion with temperature with thermistor and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2015/03/24 12:29
L56	13	55 and heat adj sink	US-PGPUB; USPAT	OR	ON	2015/03/24 11:55
L55	35	("20100030040" "20130317370" "20140066783" "20140155712" "20140296664" "0037922" "4684245" "5122925" "5625458" "5903357" "6325761" "6522521" "6639867" "6668185" "6681133" "6816010" "6912413" "7047054" "7092757" "7230227" "7365923" "7395189" "7809418" "7899506" "8044998" "8126531" "8219170" "8332006" "8380272" "8421022" "8428674" "8602971" "8688183" "8909310" "D692145").PN.	US-PGPUB; USPAT	OR	ON	2015/03/24 11:55
L54	185	LED with heat adj sink with lamp and curved and fin\$1 and mold\$3	US-PGPUB; USPAT	OR	ON	2015/03/24 11:48
L53	397	LED with heat adj sink with lamp and curved and fin\$1	US-PGPUB; USPAT	OR	ON	2015/03/24 11:35
L52	589	LED with heat adj sink with lamp and curved	US-PGPUB; USPAT	OR	ON	2015/03/24 11:35
L51	1928	LED with heat adj sink with lamp	US-PGPUB; USPAT	OR	ON	2015/03/24 11:35
L50	11057	LED with heat adj sink	US-PGPUB; USPAT	OR	ON	2015/03/24 11:35
L49	17	("2008/0266866").URPN.	USPAT	OR	ON	2015/03/24 11:34
L48	113	LED with heat adj sink with curved	US-PGPUB; USPAT	OR	ON	2015/03/24 11:26
L47	11057	LED with heat adj sink with curved	US-PGPUB; USPAT	OR	ON	2015/03/24 11:25

EAST Search History

CX-1622

L46	3504	LED with heat adj sink and curved	US-PGPUB; USPAT	OR	ON	2015/03/24 11:25
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L44	1	heat adj sink with finger with curved with fin	US-PGPUB; USPAT	OR	ON	2015/03/24 10:48
L43	34	heat adj sink with finger with curved	US-PGPUB; USPAT	OR	ON	2015/03/24 10:48
L42	1027	heat adj sink with finger	US-PGPUB; USPAT	OR	ON	2015/03/24 10:47
L31	222	heat adj sink with curved adj surface	US-PGPUB; USPAT	OR	ON	2015/03/24 10:33
L30	20	heat adj sink with molded with curved adj surface	US-PGPUB; USPAT	OR	ON	2015/03/24 10:33
L29	76	heat adj sink with molded with surface with fin\$1	US-PGPUB; USPAT	OR	ON	2015/03/24 10:19
L28	518	heat adj sink with molded with surface	US-PGPUB; USPAT	OR	ON	2015/03/24 10:19
L27	105	2 and (curv\$3) with (base substrate)	US-PGPUB; USPAT	OR	ON	2015/03/24 10:09
L26	17	25 not 24	US-PGPUB; USPAT	OR	ON	2015/03/24 10:03
L25	75	heat adj sink and spring and (600/310-344.ccls. 356/41.ccls. A61B5/1455,14551,14532.cpc.)	US-PGPUB; USPAT	OR	ON	2015/03/24 10:03
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EAST Search History

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EAST Search History

CX-1622

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		"8180420"	"8182443"	"8185180"				
		"8190223"	"8190227"	"8203438"				
		"8203704"	"8224411"	"8228181").PN.	OR			
		("8229533" "D326715" "D353195"						
		"D353196" "D356870" "D359546"						
		"D361840" "D362063" "D363120"						
		"D378414" "D390666" "D393830"						
		"D403070" "D414870" "D452012"						
		"D455834" "D463561" "D481459"						
		"D502655" "D508862" "D510625"						
		"D514461" "D535031" "D537164"						
		"D547454" "D549830" "D550364"						
		"D551350" "D553248" "D554263"						
		"D562985" "D566282" "D567125"						
		"D569001" "D569521" "D587657"						
		"D603966" "D606659" "D609193"						
		"D614305" "D621516" "RE38476"						
		"RE38492" "RE39672" "RE41317"						
		"RE41912" "RE42753" "RE43169").PN.	OR					
		("8437825").URPN.						
L16	27	finger and 600/316,323,344.ccls. and spring			US-	OR	ON	2015/03/24

EAST Search History

CX-1622

		and sink	PGPUB; USPAT			09:40
L14	996	finger and 600/316,344.ccls.	US- PGPUB; USPAT	OR	ON	2015/03/24 09:25
L5	119	2 and (flexi\$5 bend\$3 curv\$3) with (base substrate)	US- PGPUB; USPAT	OR	ON	2015/03/24 09:17
L4	16	2 and (flexi\$5 bend\$3 curv\$3) with substrate	US- PGPUB; USPAT	OR	ON	2015/03/24 09:17
L3	87	2 not 1	US- PGPUB; USPAT	OR	ON	2015/03/24 09:10
L2	453	heat adj sink with (curve\$1 arc) with fin\$1	US- PGPUB; USPAT	OR	ON	2015/03/24 09:10
L1	366	heat adj sink with (curve\$1) with fin\$1	US- PGPUB; USPAT	OR	ON	2015/03/24 09:10

EAST Search History (Interference)

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CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829,352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze et al.
	Art Unit	3777
SHEET 1 OF 2		Attorney Docket No. CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	37,922	03/17/1983	Shim	
	2	4,684,245	08/04/1987	Goldring	
	3	5,122,925	06/16/1992	Inpyn	
	4	5,222,495	06/29/1993	Clarke et al.	
	5	5,625,458	04/29/1997	Alfano et al.	
	6	5,903,357	05/11/1999	Colak	
	7	6,325,761	12/04/2001	Jay	
	8	6,522,521	02/18/2003	Abdul-Hafiz et al.	
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	10	6,668,185	12/23/2003	Toida	
	11	6,681,133	01/20/2004	Chaiken et al.	
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	27	8,428,674	04/23/2013	Duffy et al.	
	28	8,602,971	12/10/2013	Farr	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when each English language translation is attached.

Appx58691

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829,352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze et al.
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Chu Chuan Liu
SHEET 2 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29	8,688,183 (CERCA.008A)	04/01/2014	Bruinsma et al.	
	30	8,909,310 (CERCA.003D1)	12/09/2014	Lamego et al.	
	31	2010/0030040	02/04/2010	Poeze et al.	
	32	2013/0317370 (CERCA.007C1)	11/28/2013	Dalvi et al.	
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	34	2014/0296664 (CERCA.008C1)	03/27/2014	Bruinsma et al.	
	35	2014/0155712 (CERCA.003D1)	06/05/2014	Lamego et al.	
	36	D692,145	10/22/2013	Al-Ali et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	37	WO 2014/149781 (CERCA.082WO)	09/25/2014	Cercacor Laboratories, Inc.		
	38	WO 2014/158820 (CERCA.067WO)	10/02/2014	Cercacor Laboratories, Inc.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	39	Japanese Office Action, re JP Application No. 2011-516895, mailed September 2, 2014, with translation. (CERCA.007JP).	√
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	41	KANUKURTHY et al., "Data Acquisition Unit for an Implantable Multi-Channel Optical Glucose Sensor", Electro/Information Technology Conference, Chicago, IL, USA, May 17-20, 2007, pp. 1-6	
	42	SMITH, "The Pursuit of Noninvasive Glucose: 'Hunting the Deceitful Turkey'", 2006	
	43	SMALL et al., "Data Handling Issues for Near-Infrared Glucose Measurements", http://www.ieee.org/organizations/pubs/newsletters/leos/apr98/datahandling.htm , accessed 11/27/2007	

19772383
01192015

Examiner Signature	/Chu Chuan Liu/	Date Considered	03/24/2015
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

T¹ - Place a check mark in this area when a U.S. English translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	: Jeroen Poeze
App. No.	: 12/829,352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf. No.	: 8366

RESPONSE TO OFFICE ACTION DATED SEPTEMBER 17, 2014

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated September 17, 2014, Applicant respectfully submits the following amendment and comments in connection with the above-captioned application.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims which begins on page 10 of this paper.

Remarks begin on page 14 of this paper.

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Filing Date: July 1, 2010

AMENDMENTS TO THE SPECIFICATION

Changes to the specification are shown below in highlighted form, where insertions appear as underlined text (e.g., insertions) while deletions appear as strikethrough text (e.g., ~~deletions~~) or double brackets (e.g., [[deletions]]). Support for the amendments below may be found in, for example, the specifications of U.S. Patent Application Nos. 12/534,812 and 12/534,823, previously incorporated by reference into the present application as filed.

In the Specification:

Please amend the numbered paragraphs as follows:

[0002] This application is related to the following U.S. Patent Applications:

<u>App. No.</u>	<u>Filing Date</u>	<u>Title</u>	<u>Attorney Docket</u>
12/497,528	7/2/09	Noise Shielding for Noninvasive Device Contoured Protrusion for Improving	[[MLHUM]] <u>CERCA</u> .006A
12/497,523	7/2/09	Spectroscopic Measurement of Blood Constituents	[[MLHUM]] <u>CERCA</u> .007A
12/498,506	7/2/09	Heat Sink for Noninvasive Medical Sensor	[[MLHUM]] <u>CERCA</u> .011A
<u>12/534,812</u> Unknown	<u>8/3/09</u> Herewit h	Multi-Stream Sensor Front Ends for Non-Invasive Measurement of Blood Constituents	[[MLHUM]] <u>CERCA</u> .003A
<u>12/534,823</u> Unknown	<u>8/3/09</u> Herewit h	Multi-Stream Sensor for Non-Invasive Measurement of Blood Constituents	[[MLHUM]] <u>CERCA</u> .004A
<u>12/534,825</u> Unknown	<u>8/3/09</u> Herewit h	Multi-Stream Emitter for Non-Invasive Measurement of Blood Constituents	[[MLHUM]] <u>CERCA</u> .005A

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Filing Date: July 1, 2010

[0010] In an embodiment, a method of measuring an analyte based on multiple streams of optical radiation measured from a measurement site is provided. A sequence of optical radiation pulses is emitted to the measurement site. At a first location, a first stream of optical radiation is detected from the measurement site. At least at one additional location different from the first location, an additional stream of optical radiation is detected from the measurement site. An output measurement value indicative of the analyte is then determined based on the detected streams of optical radiation.

In various embodiments, the present disclosure relates to an interface for a noninvasive sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. In an embodiment, the front-end is comprised of switched-capacitor circuits that are capable of handling multiple streams of signals from the optical detectors. In another embodiment, the front-end comprises transimpedance amplifiers that are capable of handling multiple streams of input signals. In addition, the transimpedance amplifiers may be configured based on the characteristics of the transimpedance amplifier itself, the characteristics of the photodiodes, and the number of photodiodes coupled to the transimpedance amplifier.

In disclosed embodiments, the front-ends are employed in noninvasive sensors to assist in measuring and detecting various analytes. The disclosed noninvasive sensor may also include, among other things, emitters and detectors positioned to produce multi-stream sensor information. An artisan will recognize that the noninvasive sensor may have different architectures and may include or be coupled to other components, such as a display device, a network interface, and the like. An artisan will also recognize that the front-ends may be employed in any type of noninvasive sensor.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of transimpedance amplifiers configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of switched capacitor circuits configured to convert the signals from the plurality of

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detectors into a digital output signal having a stream for each of the plurality of detectors; and an output configured to provide the digital output signal.

In an embodiment, a conversion processor for a physiological, noninvasive sensor comprises: a multi-stream input configured to receive signals from a plurality of detectors in the sensor, wherein the signals are responsive to optical radiation from a tissue site; a modulator that converts the multi-stream input into a digital bit-stream; and a signal processor that produces an output signal from the digital bit-stream.

In an embodiment, a front-end interface for a noninvasive, physiological sensor comprises: a set of inputs configured to receive signals from a plurality of detectors in the sensor; a set of respective transimpedance amplifiers for each detector configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and an output configured to provide the output signal.

In certain embodiments, a noninvasive sensor interfaces with tissue at a measurement site and deforms the tissue in a way that increases signal gain in certain desired wavelengths.

In some embodiments, a detector for the sensor may comprise a set of photodiodes that are arranged in a spatial configuration. This spatial configuration may allow, for example, signal analysis for measuring analytes like glucose. In various embodiments, the detectors can be arranged across multiple locations in a spatial configuration. The spatial configuration provides a geometry having a diversity of path lengths among the detectors. For example, the detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction.

In an embodiment, a physiological, noninvasive detector is configured to detect optical radiation from a tissue site. The detector comprises a set of photodetectors and a conversion processor. The set of photodetectors each provide a signal stream indicating optical radiation from the tissue site. The set of photodetectors are arranged in a spatial configuration that provides a variation in path lengths between at least some of the photodetectors. The conversion processor that provides information indicating an analyte in the tissue site based on ratios of pairs of the signal streams.

The present disclosure, according to various embodiments, relates to noninvasive methods, devices, and systems for measuring a blood analyte, such as glucose. In the present disclosure, blood analytes are measured noninvasively based on multi-stream infrared and near-

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infrared spectroscopy. In some embodiments, an emitter may include one or more sources that are configured as a point optical source. In addition, the emitter may be operated in a manner that allows for the measurement of an analyte like glucose. In embodiments, the emitter may comprise a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In addition, in order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. The emitter may also have its duty cycle modified to achieve a desired SNR.

In an embodiment, a multi-stream emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a set of optical sources arranged as a point optical source; and a driver configured to drive the at least one light emitting diode and at least one optical source to transmit near-infrared optical radiation at sufficient power to measure an analyte in tissue that responds to near-infrared optical radiation.

In an embodiment, an emitter for a noninvasive, physiological device configured to transmit optical radiation in a tissue site comprises: a point optical source comprising an optical source configured to transmit infrared and near-infrared optical radiation to a tissue site; and a driver configured to drive the point optical source at a sufficient power and noise tolerance to effectively provide attenuated optical radiation from a tissue site that indicates an amount of glucose in the tissue site.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is transmitted at a power that is higher than the first power.

In an embodiment, a method of transmitting a stream of pulses of optical radiation in a tissue site is provided. At least one pulse of infrared optical radiation having a first pulse width is transmitted at a first power. At least one pulse of near-infrared optical radiation is then transmitted, at a second power that is higher than the first power.

[0049] The present disclosure generally relates to non-invasive medical devices. In the present disclosure, a sensor can measure various blood constituents or analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ

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visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes or percentages thereof (e.g., saturation) based on various combinations of features and components.

In various embodiments, the present disclosure relates to an interface for a noninvasive glucose sensor that comprises a front-end adapted to receive an input signals from optical detectors and provide corresponding output signals. The front-end may comprise, among other things, switched capacitor circuits or transimpedance amplifiers. In an embodiment, the front-end may comprise switched capacitor circuits that are configured to convert the output of sensor's detectors into a digital signal. In another embodiment, the front-end may comprise transimpedance amplifiers. These transimpedance amplifiers may be configured to match one or more photodiodes in a detector based on a noise model that accounts for characteristics, such as the impedance, of the transimpedance amplifier, characteristics of each photodiode, such as the impedance, and the number of photodiodes coupled to the transimpedance amplifier.

In the present disclosure, the front-ends are employed in a sensor that measures various blood analytes noninvasively using multi-stream spectroscopy. In an embodiment, the multi-stream spectroscopy can employ visible, infrared and near infrared wavelengths. As disclosed herein, the sensor is capable of noninvasively measuring blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, and the like, based on various combinations of features and components.

In an embodiment, a physiological sensor includes a detector housing that can be coupled to a measurement site, such as a patient's finger. The sensor housing can include a curved bed that can generally conform to the shape of the measurement site. In addition, the curved bed can include a protrusion shaped to increase an amount of light radiation from the measurement site. In an embodiment, the protrusion is used to thin out the measurement site. This allows the light radiation to pass through less tissue, and accordingly is attenuated less. In an embodiment, the protrusion can be used to increase the area from which attenuated light can be measured. In an embodiment, this is done through the use of a lens which collects attenuated light exiting the measurement site and focuses onto one or more detectors. The protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise. In an embodiment, such light noise includes light that would otherwise be detected at a photodetector that has not been attenuated by tissue of the measurement site of a

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patient sufficient to cause the light to adequately included information indicative of one or more physiological parameters of the patient. Such light noise includes light piping.

In an embodiment, the protrusion can be formed from the curved bed, or can be a separate component that is positionable with respect to the bed. In an embodiment, a lens made from any appropriate material is used as the protrusion. The protrusion can be convex in shape. The protrusion can also be sized and shaped to conform the measurement site into a flat or relatively flat surface. The protrusion can also be sized to conform the measurement site into a rounded surface, such as, for example, a concave or convex surface. The protrusion can include a cylindrical or partially cylindrical shape. The protrusion can be sized or shaped differently for different types of patients, such as an adult, child, or infant. The protrusion can also be sized or shaped differently for different measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like. The protrusion can thus be helpful in any type of noninvasive sensor. The external surface of the protrusion can include one or more openings or windows. The openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors. Alternatively, some of all of the protrusion can be a lens, such as a partially cylindrical lens.

The sensor can also include a shielding, such as a metal enclosure as described below or embedded within the protrusion to reduce noise. The shielding can be constructed from a conductive material, such as copper, in the form of a metal cage or enclosure, such as a box. The shielding can include a second set of one or more openings or windows. The second set of openings can be made from glass and allow light that has passed through the first set of windows of the external surface of the protrusion to pass through to one or more detectors that can be enclosed, for example, as described below.

In various embodiments, the shielding can include any substantially transparent, conductive material placed in the optical path between an emitter and a detector. The shielding can be constructed from a transparent material, such as glass, plastic, and the like. The shielding can have an electrically conductive material or coating that is at least partially transparent. The electrically conductive coating can be located on one or both sides of the shielding, or within the body of the shielding. In addition, the electrically conductive coating can be uniformly spread over the shielding or may be patterned. Furthermore, the coating can have a uniform or varying

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thickness to increase or optimize its shielding effect. The shielding can be helpful in virtually any type of noninvasive sensor that employs spectroscopy.

In an embodiment, the sensor can also include a heat sink. In an embodiment, the heat sink can include a shape that is functional in its ability to dissipate excess heat and aesthetically pleasing to the wearer. For example, the heat sink can be configured in a shape that maximizes surface area to allow for greater dissipation of heat. In an embodiment, the heat sink includes a metalized plastic, such as plastic including carbon and aluminum to allow for improved thermal conductivity and diffusivity. In an embodiment, the heat sink can advantageously be inexpensively molded into desired shapes and configurations for aesthetic and functional purposes. For example, the shape of the heat sink can be a generally curved surface and include one or more fins, undulations, grooves or channels, or combs.

[0051] In certain embodiments, multiple detectors are employed and arranged in a spatial geometry. This spatial geometry provides a diversity of path lengths among at least some of the detectors and allows for multiple bulk and pulsatile measurements that are robust. Each of the detectors can provide a respective output stream based on the detected optical radiation, or a sum of output streams can be provided from multiple detectors. In some embodiments, the sensor can also include other components, such as one or more heat sinks and one or more thermistors.

The spatial configuration of the detectors provides a geometry having a diversity of path lengths among the detectors. For example, a detector in the sensor may comprise multiple detectors that are arranged to have a sufficient difference in mean path length to allow for noise cancellation and noise reduction. In addition, walls may be used to separate individual photodetectors and prevent mixing of detected optical radiation between the different locations on the measurement site. A window may also be employed to facilitate the passing of optical radiation at various wavelengths for measuring glucose in the tissue.

In the present disclosure, a sensor may measure various blood constituents or analytes noninvasively using spectroscopy and a recipe of various features. As disclosed herein, the sensor is capable of non-invasively measuring blood analytes, such as, glucose, total hemoglobin, methemoglobin, oxygen content, and the like. In an embodiment, the spectroscopy

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used in the sensor can employ visible, infrared and near infrared wavelengths. The sensor may comprise an emitter, a detector, and other components. In some embodiments, the sensor may also comprise other components, such as one or more heat sinks and one or more thermistors.

In various embodiments, the sensor may also be coupled to one or more companion devices that process and/or display the sensor's output. The companion devices may comprise various components, such as a sensor front-end, a signal processor, a display, a network interface, a storage device or memory, etc.

A sensor can include photocommunicative components, such as an emitter, a detector, and other components. The emitter is configured as a point optical source that comprises a plurality of LEDs that emit a sequence of pulses of optical radiation across a spectrum of wavelengths. In some embodiments, the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED. In some embodiments, the emitter comprises optical sources that transmit optical radiation in the infrared or near-infrared wavelengths suitable for detecting blood analytes like glucose. In order to achieve the desired SNR for detecting analytes like glucose, the emitter may be driven using a progression from low power to higher power. In addition, the emitter may have its duty cycle modified to achieve a desired SNR.

The emitter may be constructed of materials, such as aluminum nitride and may include a heat sink to assist in heat dissipation. A thermistor may also be employed to account for heating effects on the LEDs. The emitter may further comprise a glass window and a nitrogen environment to improve transmission from the sources and prevent oxidative effects.

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AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:
 - an optical source configured to emit optical radiation onto said tissue at said measurement site;
 - at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;
 - a housing positioning said optical source and said at least one photodetector with respect to said measurement site, said housing forming a clip sensor and including:
 - a first shell housing said optical source;
 - a second shell hinged to the first shell and housing said photodetector;
 - a spring disposed between and urging together the shells;
 - a heat sink integrated as a single piece with the first shell of said housing, the heat sink molded into a curved outer surface of the first shell and including one or more curved fins; and
 - a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site.
2. **(Original)** The sensor of claim 1, wherein said tissue at said measurement site comprises a digit of said patient.
3. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is reusable.
4. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is disposable.
5. **(Previously Presented)** The sensor of claim 1, comprising a cable connected to a patient monitor configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters.
6. **(Original)** The sensor of claim 5, wherein one of the one or more physiological parameters comprises total hemoglobin.

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7. **(Original)** The sensor of claim 5, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

8. **(Original)** The sensor of claim 1, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

9. **(Original)** The sensor of claim 1, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

10. **(Currently Amended)** A method of measuring an analyte and a temperature at a measurement site of a living patient, said method comprising:

emitting optical radiation on the measurement site from a first shell of a clip-type sensor;

detecting said optical radiation after attenuation by tissue at the measurement site in a second shell of the clip-type sensor, the first shell hinged to the second shell;

dissipating heat from the first shell using a heat sink integrated as a single piece with the first shell, the heat sink molded into a curved outer surface of the first shell and including one or more curved fins;

measuring the temperature of said measurement site;

using a signal processor, determining an indication of perfusion from said temperature measurement; and

determining an output measurement value indicative of the analyte based on the detected streams of optical radiation.

11. **(Previously Presented)** The method of claim 10, wherein said tissue at said measurement site comprises a digit of said patient.

12. **(Previously Presented)** The method of claim 10, wherein the method further comprises correcting wavelength drift after attenuation by said tissue.

13. **(Previously Presented)** The method of claim 10, wherein said analyte comprises total hemoglobin.

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14. **(Currently Amended)** A signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the system comprising:

a noninvasive clip-type optical sensor including:

a housing including a first shell, a second shell hinged to the first shell and a spring disposed between and urging together the shells;

an optical source configured to emit optical radiation onto said tissue at said measurement site and housed in the first shell;

a heat sink integrated as a single piece with the first shell, the heat sink molded into a curved outer surface of the first shell and including one or more curved fins;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation, the at least one photodetector housed in the second shell;

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site;

a monitor configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters; and

a cable connected to the monitor providing communication between said optical sensor and said monitor.

15. **(Original)** The system of claim 14, wherein said tissue at said measurement site comprises a digit of said patient.

16. **(Original)** The system of claim 14, wherein at least a portion of said sensor is reusable.

17. **(Original)** The system of claim 14, wherein at least a portion of said sensor is disposable.

18. **(Original)** The system of claim 14, wherein one of the one or more physiological parameters comprises total hemoglobin.

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19. **(Original)** The system of claim 14, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

20. **(Original)** The system of claim 14, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

21. **(Original)** The system of claim 14, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

22. **(Previously Presented)** The system of claim 14, wherein said monitor comprises a handheld monitor.

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Filing Date: July 1, 2010

REMARKS

By way of summary, Claims 1-22 were pending in this application. In the present amendment, the Applicants have amended Claims 1, 10, and 14. Accordingly, Claims 1-22 remain pending for consideration.

Claim Rejections Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1-5 and 7-8 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,362,966 to Rosenthal (“Rosenthal”) in view of U.S. Patent No. 7,254,434 to Schulz et al. (“Schulz”) and further in view of U.S. Patent No. 5,131,391 to Sakai et al. (“Sakai”); Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Schulz, and Sakai, and further in view of U.S. Patent No. 5,851,178 to Aronow (“Aronow”); Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Schulz, and Sakai, and further in view of U.S. Patent No. 6,606,509 to Schmitt (“Schmitt”); Claims 10-12, 14-17, and 19-20 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Schulz, and Sakai, and further in view of U.S. Patent Publication No. 2004/0039271 to Blank et al. (“Blank”); Claims 13 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Schulz, Sakai, and Blank, and further in view of Aronow; Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Schulz, Sakai, and Blank, and further in view of Schmitt; and Claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Schulz, Sakai, and Blank, and further in view of U.S. Patent Publication No. 2006/0220881 to Al-Ali (“Al-Ali”). Applicant respectfully traverses these rejections, the characterization of the pending claims, and each and every implicit and/or explicit potential for reliance on Official Notice. In view of the foregoing amendments and for at least the reasons set forth below, Applicant respectfully disagrees and requests reconsideration of the aforementioned claims.

Any Combination of the Cited References Fails to Teach or Suggest All Elements

While each of Claims 1, 10, and 14 varies in scope from one another, each has been amended to recite, *inter alia*, a “heat sink molded into a curved outer surface of the first shell and including one or more curved fins.” An embodiment of Claim 1 is shown, for example, in Fig. 2B, reproduced below. As shown in the example embodiment of Fig. 2B, a heat sink is molded

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into a curved outer surface of the first shell of the clip sensor and includes one or more curved fins.

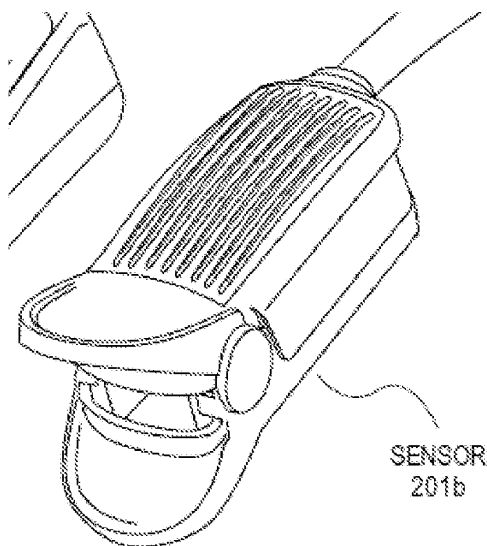


FIG. 2B

In contrast, any combination of the cited references fails to teach or suggest such a feature. Rather, for example, Sakai teaches “a probe which is adapted to be set on a body surface 12 of a subject with the help of a band.” *Sakai*, c. 3, ll. 29-31. The probe in Sakai is disclosed as having a heating element, such as “a Peltier's element 70,” that is used such that a “temperature of the heat conductor body 26 is advantageously maintained at a temperature equal to the reference value” such as “a normal or mean deep body temperature of human beings.” *Id.*, c. 8, ll. 23-68. Further, the “Peltier's element 70 is disposed on an upper surface of a heat conductor body 26,” and “an upper surface of the Peltier's element 70 is disposed a fin 72 serving for radiating heat.” *Id.*, c. 8, ll. 23-27. Thus, although Sakai discloses a heating element with a fin, Sakai fails to teach or suggest a “heat sink molded into a curved outer surface of the first shell and including one or more curved fins.” Additionally, none of the other cited references makes up for the deficiencies of Sakai. Accordingly, as the cited references fails to teach or suggest all the independent claim limitations, Applicant requests the Section 103 rejections of Claims 1, 10, and 14 be withdrawn.

Applicant additionally requests the Section 103 rejections of each of the dependent claims be withdrawn at least for reasons similar to those discussed above with respect to Claims 1, 10, and 14, and for the unique patentable features recited by each.

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Summary

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicant's undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicant's attorney can be reached at (949) 721-2812 or at the number listed below.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
CERCA.004C3	14/064055	MULTI-STREAM SENSOR FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	10/25/2013
CERCA.006C1	14/069974	NOISE SHIELDING FOR A NONINVAISE DEVICE	11/01/2013
CERCA.007C1	13/888266	CONTOURED PROTRUSION FOR IMPROVING SPECTROSCOPIC MEASUREMENT OF BLOOD CONSTITUENTS	05/06/2013

Application No.: 12/829,352
Filing Date: July 1, 2010

Docket No.	Serial No.	Title	Filed
CERCA.008C1	14/227230	EMITTER DRIVER FOR NONINVASIVE PATIENT MONITOR	03/27/2014

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 19, 2015

By: /Scott Cromar/_____
Scott A. Cromar
Registration No. 65,066
Attorney of Record
Customer No. 20995
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19757277

Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Scott Cromar			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 1 month with \$0 paid	1251	1	200	200
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				380

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	21244339
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Scott Cromar/Daniela Lopez
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Attorney Docket Number:	CERCA.002C1
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<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

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Appx58712

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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	WO2014149781.PDF	2628332	no	45
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Warnings:					
Information:					
2	Foreign Reference	WO2014158820.PDF	3040868	no	48
			f9d7b23a8d4e744c0c07e68733f5f7e0494e8fad		
Warnings:					
Information:					
3	Other Reference-Patent/App/Search documents	2014_10_02_JP_OA_wTrans_CERCA_007JP.PDF	290617	no	6
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Warnings:					
Information:					
4	Other Reference-Patent/App/Search documents	OA_EP10763901-5_2014-08-27.PDF	171649	no	4
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Warnings:					
Information:					
5	Non Patent Literature	KANUKURTHY.PDF	969914	no	6
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6	Non Patent Literature	SMALL.PDF	267787	no	4
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7	Non Patent Literature	SMITH_2006.PDF	6827361	no	129
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CX-1622

8		CERCA-002C1_IDS.pdf	128685 fd0cdfa9087667ddc92f6e4beab35e5bc67a6582	yes	4
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	Document Description		Start	End	
	Transmittal Letter		1	2	
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9	Application Data Sheet	CERCA-002C1_Supp_ADS.pdf	144901 0576312a8e479e959aecc5a22f88639ee7a06330	no	7
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	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Specification		2	9	
	Claims		10	13	
	Applicant Arguments/Remarks Made in an Amendment		14	17	
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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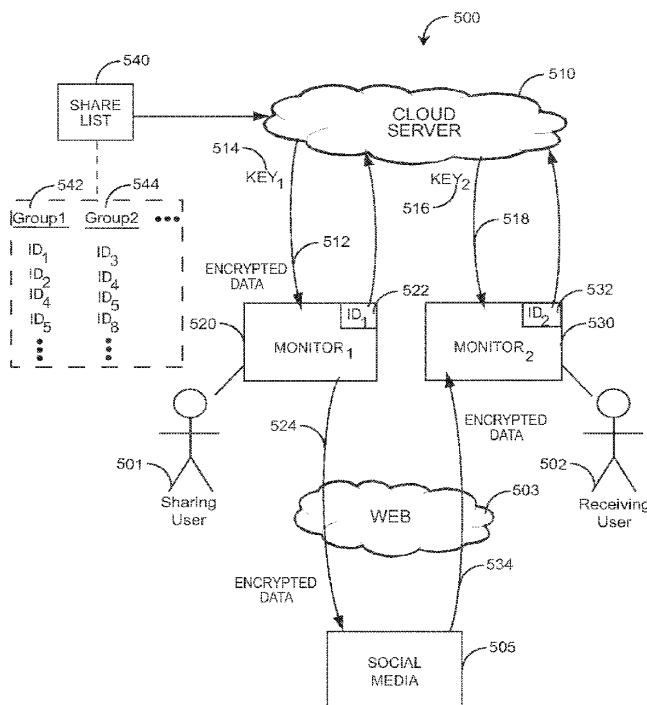
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HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
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ZW.

[Continued on next page]

(54) Title: CLOUD-BASED PHYSIOLOGICAL MONITORING SYSTEM



(57) Abstract: A cloud-based physiological monitoring system has a sensor in communications with a living being so as to generate a data stream generally responsive to a physiological condition of the living being. A monitor receives the data stream from the sensor and transmits the data stream to a cloud server. The cloud server processes the data stream so as to derive physiological parameters having values responsive to the physiological condition. The cloud server derives a medical index based upon a combination of the physiological parameters. The cloud server communicates the medical index to the monitor, which displays the medical index.

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CLOUD-BASED PHYSIOLOGICAL MONITORING SYSTEM

PRIORITY CLAIM AND REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 61/801,464, filed 03/15/2013, titled *Cloud-Based Blood Glucose Monitoring System*; U.S. Provisional Patent Application Serial No. 61/841,346, filed 06/30/2013, titled *Cloud-Based Monitoring System*; U.S. Provisional Patent Application Serial No. 61/885,491, filed 10/01/2013, titled *Cloud-Based Monitoring System*; and U.S. Provisional Patent Application Serial No. 61/922,861, filed 01/01/2014, titled *Cloud-Based Physiological Index Monitoring System*; all of the above-referenced provisional patent applications are hereby incorporated in their entireties by reference herein.

BACKGROUND OF THE INVENTION

[0002] Medical device manufacturers are continually increasing the processing capabilities of physiological monitors that process signals based upon the attenuation of light by a tissue site. In general, such physiological monitoring systems include one or more optical sensors that irradiate a tissue site and one or more photodetectors that detect the optical radiation after attenuation by the tissue site. The sensor communicates the detected signal to a physiological monitor, which removes noise and preprocesses the signal. Advanced signal processors then perform time domain and/or frequency domain processing to determine blood constituents and other physiological parameters.

[0003] Manufacturers have advanced basic pulse oximeters from devices that determine measurements for blood oxygen saturation ("SpO₂"), pulse rate ("PR") and plethysmographic information to read-through-motion oximeters and to co-oximeters that determine measurements of many constituents of circulating blood. For example, Masimo Corporation of Irvine Calif. ("Masimo") manufactures pulse oximetry systems including Masimo SET[®] low noise optical sensors and read through motion pulse oximetry monitors for measuring SpO₂, pulse rate (PR) and perfusion index (PI). Masimo optical sensors include any of Masimo LNOP[®], LNCS[®], SofTouch[™] and Blue[™] adhesive or reusable sensors. Masimo pulse oximetry monitors include any of Masimo Rad-8[®], Rad-5[®], Rad[®]-5v or SatShare[®]

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monitors. Such advanced pulse oximeters and low noise sensors have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training and virtually all types of monitoring scenarios.

[0004] Many innovations improving the measurement of blood constituents are described in at least U.S. Pat. Nos. 6,770,028; 6,658,276; 6,157,850; 6,002,952; 5,769,785 and 5,758,644, which are assigned to Masimo and are incorporated in their entireties by reference herein. Corresponding low noise optical sensors are disclosed in at least U.S. Pat. Nos. 6,985,764; 6,088,607; 5,782,757 and 5,638,818, assigned to Masimo and hereby incorporated in their entireties by reference herein.

[0005] Advanced blood parameter measurement systems include Masimo Rainbow[®] SET, which provides measurements in addition to SpO₂, such as total hemoglobin (SpHb[™]), oxygen content (SpOC[™]), methemoglobin (SpMet[®]), carboxyhemoglobin (SpCO[®]) and PVI[®]. Advanced blood parameter sensors include Masimo Rainbow[®] adhesive, ReSposable[™] and reusable sensors. Advanced blood parameter monitors include Masimo Radical-7[™], Rad-87[™] and Rad-57[™] monitors, all available from Masimo. Advanced blood parameter monitors further include Masimo Rainbow 4D[™] DC sensors and Masimo Pronto[®] and Pronto-7[®] monitors for noninvasive and quick spot checking of total hemoglobin (SpHb[®]), SpO₂, pulse rate and perfusion index).

[0006] Advanced parameter measurement systems may also include acoustic monitoring such as acoustic respiration rate (RRa[™]) using a Rainbow Acoustic Sensor[™] and Rad-87[™] monitor, available from Masimo. An advanced parameter measurement system that includes acoustic monitoring is described in U.S. Pat. Pub. No. 2010/0274099, filed December 21, 2009, titled *Acoustic Sensor Assembly*, assigned to Masimo and incorporated in its entirety by reference herein.

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[0007] Innovations relating to other advanced blood parameter measurement systems are described in at least U.S. Pat. 7,647,083, filed March 1, 2006, titled *Multiple Wavelength Sensor Equalization*; U.S. Pat. No. 7,729,733, filed March 1, 2006, titled *Configurable Physiological Measurement System*; U.S. Pat. Pub. No. 2006/0211925, filed March 1, 2006, titled *Physiological Parameter Confidence Measure* and U.S. Pat. Pub. No. 2006/0238358, filed March 1, 2006, titled *Noninvasive Multi-Parameter Patient Monitor*, all assigned to Cercacor Laboratories, Inc., Irvine, CA (Cercacor) and all incorporated in their entireties by reference herein.

SUMMARY OF THE INVENTION

[0008] One aspect of a cloud-based physiological monitoring system is a sensor in communications with a living being so as to generate a data stream generally responsive to a physiological condition of the living being. A monitor receives the data stream from the sensor and transmits the data stream to a cloud server. The cloud server processes the data stream so as to derive parameters having values responsive to the physiological condition. The cloud server derives a medical index based upon a combination of the parameters. The cloud server communicates the medical index to the physiological monitor and the physiological monitor displays the medical index.

[0009] In an embodiment, the cloud-based physiological monitoring system sensor comprises an optical sensor and the parameters comprise a blood constituent parameter. The parameters comprise a plethysmograph waveform parameter. A blood pressure sensor is in communications with the living being, and a blood pressure monitor receives a blood pressure data stream from the blood pressure sensor and transmits the blood pressure data stream to the cloud server. The cloud server processes the blood pressure data stream so as to derive a blood pressure parameter having a blood pressure value responsive to the physiological condition and the parameters further comprise the blood pressure parameter.

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[0010] In various other embodiments, the medical index is based upon trends of the combination of the parameters. The blood constituents include Hgb, BUN and Cr. The medical index relates to at least one of hydration, cardiovascular risk and renal insufficiency. In a particular embodiment, the medical index relates to at least one of dehydration, over hydration, gastrointestinal bleeding and congestive heart failure exacerbation.

[0011] Another aspect of a cloud-based physiological monitoring system comprises generating sensor data generally responsive to a physiological phenomenon of a living being, communicating the sensor data to a local medical device and transmitting the sensor data from the local medical device to a remote cloud server. The system further comprises processing the sensor data at the cloud server so as to derive parameters having values responsive to the physiological phenomenon and trending the parameters at the cloud server so as to derive a medical index responsive to the parameters, where the medical index indicates a medical condition. The system additionally comprises communicating the medical index to the local medical device and displaying the medical index on the local medical device.

[0012] In various embodiments, cloud-based physiological monitoring system comprises generating second sensor data generally responsive to a second physiological phenomenon of a living being, communicating the second sensor data to a second local medical device and transmitting the second sensor data from the second local medical device to the remote cloud server. The system further comprises processing the second sensor data at the cloud server so as to derive a second parameter having values responsive to the second physiological phenomenon and trending the second parameter with at least one of the parameters at the cloud server so as to improve the efficacy of the medical index. In various other embodiments, generating sensor data comprises optically-deriving data responsive to pulsatile blood flow. Generating second sensor data comprises air-cuff-deriving data responsive to blood pressure. The system further comprises time frame matching the sensor data and the second sensor data at the cloud server. In a particular embodiment, displaying the medical index comprises indicating hydration on a smart cellular telephone.

[0013] A further aspect of a cloud-based physiological monitoring system comprises a physiological monitor in remote communications with a cloud server,

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where the physiological monitor inputs sensor data responsive to a physiological condition of a user. The cloud server is in remote communications with the physiological monitor so as to upload the sensor data. The cloud server executes signal processing algorithms so as to derive a physiological parameter from the sensor data. The cloud server downloads the physiological parameter to the physiological monitor for display to user.

[0014] In various embodiments, the physiological monitor has an online application that executes if the cloud server is available and, if so, the online application inputs sensor data from a physiological sensor in communications with the physiological monitor, transmits the sensor data to the cloud server, receives a parameter value that the cloud server derives from the sensor data and displays the parameter value on the physiological monitor. The physiological monitor has an offline application that executes if the cloud server is unavailable and, if so, the offline application inputs sensor data from a physiological sensor in communications with the physiological monitor, calculates a parameter value from the sensor data and displays the parameter value on the physiological monitor.

[0015] In various further embodiments, the online application performs an initial blood glucose calibration phase of the physiological monitor that comprises repeated blood sample data derived from a strip reader over an initial calibration period of several weeks and repeated optical sensor data corresponding to the blood sample data. The blood sample data and the sensor data are transmitted to the cloud server and the cloud server correlates the blood sample data and the sensor data during the initial calibration stage. The online application further performs an end blood glucose calibration phase of the physiological monitor that comprises optical sensor data occasionally interspersed with blood sample data. The sensor data and occasional blood sample data are transmitted to the cloud server, which updates the calibration as needed.

[0016] In additional embodiments, a share user establishes a receive user who is allowed to view the share user's medical information. A share ID is associated with the share user's physiological monitor. A receive ID is associated with the receive user's physiological monitor. The cloud server associates the share ID with the receive ID. The cloud server encrypts the share user's medical information according to a share key based upon the share ID.

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The cloud server generates a decryption key based upon the receive ID. The cloud server transmits the encrypted medical information and share key to the share user. The cloud server transmits the receive key to the receive user. The share user posts the encrypted medical information to a public website, the receive user downloads the encrypted medical information and the receive user decrypts the medical information using the receive key.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0017] **FIGS. 1A-B** are perspective views of cloud-based monitoring systems that are capable of blood parameter and blood pressure monitoring;

[0018] **FIG. 2** is a general flow diagram of a cloud-based monitoring system;

[0019] **FIG. 3** is a detailed block diagram of a cloud-based monitoring system;

[0020] **FIGS. 4A-B** are general flow diagrams of blood glucose calibration;

[0021] **FIG. 5** is a general flow diagram of a cloud-based, protected social network for sharing monitoring measurements;

[0022] **FIG. 6** is a general flow diagram of real-time algorithm processing using one or more of a sensor and connected medical device or a smart sensor and connected mobile or desktop device in communications with a cloud service so as to perform clinical services including physiological parameter calculations;

[0023] **FIG. 7** is a general flow diagram of real-time algorithm processing using multiple sensors and connected medical devices in communications with a cloud service so as to perform clinical services including calculations of medical indices;

[0024] **FIG. 8A-F** are medical index tables illustrating trends in blood-related parameters, plethysmograph waveform features and blood pressure that are indicative of dehydration, renal insufficiency, over-hydration, gastrointestinal bleeding, congestive heart failure exacerbation and cardiovascular risk, respectively.

[0025] **FIG. 9** is a comprehensive medical index table illustrating trends in various physiological measurements, including blood-constituents and oxygen saturation, blood pressure, respiration rate (RR), temperature and heart-related parameters including heart rate (HR) and electrocardiogram (ECG) waveform features indicative of various physiological conditions, maladies and diseases.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] **FIGS. 1A-B** illustrate cloud-based physiological monitoring systems that are capable of blood parameter, blood pressure and other physiological measurements. As shown in **FIG. 1A**, a physiological monitoring system 101 advantageously provides spot check measurements of various blood constituents, such as blood glucose. The monitoring system 101 has a blood parameter monitor 130, an optical sensor 140, a sensor cable 150 electrically and mechanically interconnecting the monitor 130 and sensor 140 and a monitor-integrated test strip reader 160 that accepts test strips 165 via a test strip slot. In a particular use, the monitoring system 101 provides relatively frequent noninvasive measurements of blood glucose interspersed with relatively infrequent invasive measurements of blood glucose so as to manage individual blood glucose levels. The monitoring system 101 individually calibrates the sensor 140 measurements with intermittent test strip measurements to advantageously provide the accuracy of individualized glucose test strip measurements at a much-reduced frequency of blood draws. Reduced blood draws are a substantial aid to persons who require frequent monitoring of blood glucose levels to manage diabetes and related diseases. In an embodiment, the monitor 130 has a handheld-tablet housing including an integrated 5.6in IPS touch screen 135 defining one or more input keys and providing a display of blood glucose levels among other features. The monitor 130 advantageously has Wi-Fi and 3G cellular communications for cabled and wireless cloud access. Cloud connectivity allows remote sensor data processing, algorithm development, individual blood glucose calibration and software updates among other cloud services. A blood parameter monitoring system is described with respect to US Pat. App. No. 13/646,659, filed 10/05/2012, titled *Noninvasive Blood Analysis System* and US Pat. App. No. 13/726,539, filed 12/24/2012, titled *Blood Glucose Calibration System*, both assigned to Cercacor and both incorporated in their entireties by reference herein.

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[0027] As shown in **FIG. 1B**, a physiological monitoring system 102 may have two or more monitors 170, 180 in sensor communications with an individual person so as to generate multiple sensor data streams and display multiple types of physiological parameters. In an embodiment, the multiple monitors 102 include a handheld blood parameter monitor 170 and a arm cuff-mounted blood pressure monitor 180. In an embodiment, the handheld blood parameter monitor 170 has an optical sensor 172, a monitor module 174 and a handheld smart cellular telephone ("smart phone") 176. An optical sensor is described above with respect to FIG. 1A. The optical sensor attaches to a fleshy tissue site, such as a fingertip. The monitor module 174 drives LEDs in the optical sensor 172 and receives detector signals responsive to the LED emitted light after attenuation by the fleshy tissue and blood flow within the fleshy tissue. The blood flow may be active-pulsed and arterial-pulse blood flow. The monitor module 174 receives the detector signals, i.e. the raw sensor data stream and derives physiological parameters, which are communicated to the smart phone 176. This alleviates the smart phone 176 from the computationally-intense task of processing raw sensor data and deriving physiological parameters, which the current generation of smart phones are ill-equipped to perform. A combination optical sensor, monitor module and smart phone configured as a mobile physiological monitor are described in U.S. Patent App. No. 14/033,315, titled *Physiological Monitor with Mobile Computing Device Connectivity*, assigned to Cercacor and incorporated in its entirety by reference herein.

[0028] Also shown in **FIG. 1B**, in an embodiment, a cuff-mounted, blood pressure monitor 180 is attached to a person's limb so as to measure blood pressure parameters. The blood pressure monitor 180 has a monitor module 182, an inflatable cuff 184 and a gas chamber 186. The monitor module 182 is mounted to the inflatable cuff 184, is battery-operated and includes a display and a user interface. In an embodiment, the gas chamber 186 is configured for disposable CO₂ cartridges 188 in communications with a monitor-controlled gas valve for automatic cuff inflation. Also shown in **FIG. 1B**, the blood pressure monitor 180 has an OLED display, a 16g CO₂ canister 188 for automatic cuff information, and Bluetooth and USB communication interfaces. Sensor capabilities include systolic and diastolic blood pressure parameters, pulse rate and mean arterial pressure (MAP). The blood pressure monitor 180 also has

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cloud communications capabilities either directly via a wireless wide area communications link or via local area communications (e.g. Wi-Fi, Bluetooth) with other devices that have such a wide area link, such as the smart phone 176. A cuff-mounted monitor is described in detail in U.S. Pat. App. No. 13/838,225, filed 03/15/2013, titled *Patient Monitoring System*, assigned to Cercacor and incorporated in its entirety by reference herein. These cloud-based physiological monitors 101-102 (FIGS. 1A-B) advantageously provide measurement capabilities for more than a dozen different noninvasive parameters in addition to cloud services including clinical data visualization, storage and exchange and real-time algorithm processing.

[0029] Further shown in **FIG. 1B**, a multiple-monitor configuration 102 can advantageously derive multiple sensor 170, 180 data streams and multiple physiological parameters from the same individual and communicate these data streams and parameters to the cloud, as described in further detail with respect to FIGS. 2-7, below. This advantageously allows a cloud-based processor to receive two or more independent sensor data streams, for example data from a blood pressure sensor and an optical sensor attached to an individual, and derive cross-sensor parameters such as the medical indices described below. Such cross-sensor parameters allow caregivers to assess a broader spectrum of physiological conditions from states and trends in these cross-sensor parameters than possible with a data stream from a single sensor.

[0030] Although a multiple-monitor configuration 102 is described above with respect to a blood pressure sensor and an optical sensor, each in communications with their individual monitors, in other embodiments, multiple sensors may be in communications with a single monitor. These sensors may include a variety of devices including accelerometers for data regarding body position and activity; body and environment temperature sensors; electrical sensors for deriving EEG, EKG data streams; acoustic sensors for detecting respiration and other body sounds; and capnography sensors for monitoring carbon dioxide, among others.

[0031] Additionally shown in **FIG. 1B**, in an embodiment, individual monitors 170, 180 may each communicate directly to the cloud utilizing wide area communications, such as wired or wireless Internet or cellular network devices. In an embodiment, a first monitor 170 may have wide area communications

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capability, and a second monitor 180 may use local area communications to communicate its sensor data to the first monitor 170 for transmission to a cloud-based processor. In another embodiment, first 170 and second 180 monitors may each use local area communications to communicate sensor data to a local processing device, such as a laptop or desktop computer that, in turn, uses wide area communications to communicate with a cloud-based processor. Various monitor-cloud data communications and processing scenarios are further described with respect to FIGS. 2-7, below.

[0032] FIG. 2 illustrates a cloud-based monitoring system 200 having a cloud server 210 in communications with physiological monitors 201-204, such as described with respect to FIGS. 1A-B, above. The monitors 201-204 are located in various hospital/clinic 220, home 230 and street 240 locations remote from the cloud server 210. In an embodiment, the cloud server 210 utilizes various sensor signal processing algorithms to estimate physiological parameters such as blood oxygen saturation, carboxyhemoglobin, methomoglobin, blood glucose, total hemoglobin and respiration rate, to name just a few. These parameters are derived from sensor data collected by the monitors 201-204 and transmitted to the cloud server 210 via various data transmission paths.

[0033] As shown in FIG. 2, data is transmitted from monitors 201-204 to the cloud server 210 via wired (e.g. LAN 223) or wireless (e.g. Wi-Fi 225) local networks to wide area media, such as Internet cable 224 or telecommunications (e.g. 3G 226) networks. Alternatively, a monitor 204 may have a wireless link 242 for direct data transmission to the cloud over a cellular network. These wide area media, in turn, are in communications with the cloud server 210, which calculates physiological parameters as described above. The calculated parameters are transmitted back to the monitors 201-204 or smart phone 205 for display, additional processing and storage of physiological parameters as well as corresponding notification and use by patients and their care providers.

[0034] Further shown in FIG. 2, the above-described configurations allow all monitors 201-204 to benefit from the same set of signal processing algorithms residing in the cloud server 210. At the same time, these signal processing algorithms can remain proprietary and protected from reverse engineering in the event any monitors 201-204 are lost or stolen, as the monitors 201-204 do not have access to the cloud algorithms. In particular, the monitors 201-204 only

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have access to raw (sensor) data, error messages and data pre-processing (e.g. for probe-off detection). In other embodiments, non-proprietary signal processing algorithms are resident in the monitors 201-204 and proprietary algorithms are resident in the cloud 210. In an embodiment, a dual communications channel between one or more monitors 201-204 and the cloud 210 may be implemented for redundancy, so as to resolve safety issues related to critical medical information and potential communication or monitor malfunctions. For example, a direct 3G (telecommunications) link between a monitor 201-204 and the cloud server 210 may be available as backup to landline communications.

[0035] FIG. 3 illustrates a cloud-based physiological monitoring system 300 including a monitor 301, a monitoring community 302 and a monitoring center 303. A monitor 301 is in communications with one or more sensors, as described with respect to FIGS. 1A-B, above. In an embodiment, the monitor 301 includes medical technology 305 in addition to non-medical computer and telecommunication functions such as are available on any of various mobile consumer devices (not shown). Medical technology 305 includes both an offline application 310 and an online application 350 for measuring and managing blood glucose, blood pressure and other physiological parameters and medical indices.

[0036] As shown in FIG. 3, following successful calibration, the offline application 310 allows a patient to attach a sensor, e.g. 140 (FIG. 1A), push a monitor button, e.g. "Test," and initiate a sampling of sensor data and derivation of physiological parameters, such as blood glucose, utilizing resident processors and algorithms. The monitor 301 then displays the resulting physiological parameter value on a monitor display, e.g. 135 (FIG. 1A). The only "cloud" function the offline app 310 performs is to occasionally dump patient data, including derived physiological parameters and related information, from its database 322 to, say, a treating physician's database 342, so that the physician can monitor and review the patient's disease management and insure that the monitor and sensor are functioning normally. This feature also allows a patient to share their medical information with other members of the monitoring community 302, including family members or non-related persons having similar treatments and therapies, as described with respect to FIG. 5, below.

[0037] Also shown in FIG. 3, an online application 350 advantageously transmits the monitor 301 sensor data via the cloud (e.g. Internet 304) to the

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monitoring center 303, which is remote from the monitor 301 location. Physiological parameter processing algorithms reside in a secure server 390, which derives blood glucose values, other blood constituent values and measurements of other physiological parameters, such as blood pressure, with very small latency times. A data buffer 362 in the monitor 301 reduces transmit data latency times. The calculated physiological parameter results are immediately returned to the monitor 301 for display.

[0038] Further shown in **FIG. 3**, the monitoring center 303, which is accessed via the online application 350, has more processing power and is easier to maintain than the offline application 310. In particular, algorithm 390 modifications and upgrades can be made simply and quickly at the monitoring center 303 site as compared to upgrades across many monitors 301 distributed over disparate locations. Further, the monitoring center 303 processors have significantly greater computational capabilities than the relatively limited processors residing in each monitor 301. Also, algorithms developed at the monitor manufacturer's facility typically have to be reduced in size and ported to a different programming language for installation in each monitor 301, which requires speed and memory size tradeoffs that are nonexistent at the monitoring center 303. In addition, the processor intensive computations required for offline applications raise heat dissipation issues for relatively compact handheld and tablet monitors. The downside of the monitoring center 303 is the necessity of reliable connectivity to all of the monitors 301.

[0039] According to the trade-offs described above, in a particularly advantageous embodiment, the online application 350 is utilized for cloud computing of all physiological parameters or at least the most computationally intense parameters unless cloud access is temporarily unavailable. In the event the monitoring center 303 processors are down or the online application 350 communications link with the monitoring center 303 is lost, then the offline application 310 performs the necessary computations. This can be done in an emergency for a few minutes without concern about monitor 301 heat dissipation limitations. Further, for blood glucose measurements, loss of cloud access is mitigated somewhat by the device strip reader 160 (**FIG. 1A**), which is always available to users in the event the monitoring center 303 is "down" or when a particular monitor 301 has no cloud access.

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[0040] In a particularly advantageous blood glucose management embodiment, the offline application 310 has a setting for the maximum time allowed between invasive (test strip) measurements of blood glucose. The offline application 310 tracks the time that has elapsed since the last test strip measurement was made and disables noninvasive blood glucose monitoring if that elapsed time limit is exceeded. In an embodiment, the offline application 310 provides a user one or more warning messages of an impending noninvasive measurement timeout due to an excessive elapsed time from the last invasive measurement. In an embodiment, either the offline application 350 or the online application 310 may adjust the maximum time allowed between invasive measurements as a function of the delta time and the delta blood glucose values between two consecutive invasive measurements. This maximum elapsed time adjustment advantageously takes into account relatively small changes, historically, in invasive glucose values over relatively long time spans so as to lengthen the maximum-allowed elapsed time between invasive measurements. Likewise, the maximum elapsed time adjustment takes into account relatively large changes, historically, in invasive glucose values over relatively short time spans so as to shorten the maximum-allowed elapsed time between invasive measurements.

[0041] **FIGS. 4A-B** illustrate a blood parameter calibration process 401-402 that includes set-up and calibration functions for a cloud-based physiological monitor, such as described with respect to FIGS. 1-3, above. **FIG. 4A** illustrates an initial calibration stage 401 when a new user attempts to calibrate their monitoring system, e.g. 101 (FIG. 1A) using a strip reader 160 and test strip 165 (FIG. 1A). At regular intervals, blood samples are read with a strip at the same time that optical sensor 140 (FIG. 11) data is taken 410. An online application 412 sends the strip and sensor data to a cloud server 414. See, e.g., 303, 350 (FIG. 3). The strip readings are then compared to calculations based upon optical sensor 140 (FIG. 1A) measurements. If there are consistent matches between the invasive and noninvasive measurements, the calibration stage 401 is complete. If not, the calibration stage 401 continues. This process may take 1 to 6 weeks and, in some cases, may not be successful. That is, after some predetermined number of measurements or calibration time interval, the strip readings may not correlate with the optical sensor-based measurements. As a

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result, that particular individual is deemed not suitable for noninvasive glucose monitoring. **FIG. 4B** illustrates an ongoing use 402 once the user is initially calibrated 401. The cloud server 434 indicates to the online application 432 that the user is calibrated 401. The monitoring system 101 (FIG. 1A) is enabled accordingly 430 to use sensor-based measurements with occasional strip measurements to insure up-to-date calibration. This calibration process 401, 402 is particularly advantageous with respect to calibrating a cloud-based physiological monitor for noninvasive (optical sensor) blood glucose measurements interleaved with occasional invasive (glucose test strip) measurements.

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[0042] FIG. 5 illustrates a cloud-based, secure social network 500 that enables a monitor 101-102 (FIGS. 1A-B) user to confidentially share their medical information with a trusted group of other users. Medical information may include measured physiological parameters and a user's health management experiences. For example, medical information may be a past history of blood glucose measurements; steps taken to control blood glucose, including medication, diet and exercise; and recent blood glucose measurement results. The social media 505 for sharing this medical information may be any of the popular social media sites, such as Facebook or Google+, to name a few. The protected social network 500 incorporates cloud-based monitors 520, 530 in communications with a cloud server 510, as described with respect to FIGS. 1-4, above.

[0043] As shown in FIG. 5, each sharing user 501 communicates with the cloud server 510 so as to establish a share list 540 of one or more groups 542, 544 of receiving users 502 who are allowed to view the sharing user's medical information. Receiving user groups 542, 544 may be based upon, or restricted by, the type and scope of medical information shared. Each user 501, 502 is advantageously identified according to their monitor device ID 522, 532, which is securely registered with the cloud server 510. That is, one advantage of a cloud-based secure social network 500 is that only individuals assigned a monitor 520, 530 can belong, and membership in and use of the protected social network 500 is enforced by the cloud server 510 and its recognition of monitor IDs 522, 532. Accordingly, a sharing user's share list 540 securely establishes monitors 530 that receive monitoring data and other personal information regarding the sharing user 501.

[0044] Also shown in FIG. 5, the cloud server 510 advantageously manages encryption of share data according to the sharing user 501 and their share list 540. The cloud server 510 collects and stores monitoring device 520 data and calculates and stores corresponding measurement results, which may include share data. The cloud server 510 encrypts share data 512, which is transmitted from the cloud to the sharing user's monitor 520. A corresponding KEY₁ 514 based upon the sharing user's monitoring device ID₁ 522 is also transmitted to the sharing user's device 520. This allows the sharing user 501 to decrypt and view share data. A separate KEY₂ 516 is transmitted to a monitor 530

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corresponding to a receiving user 502 listed on the share list 542. The cloud server 510 generates KEY₂ 516 according to the receiving user's device ID₂ 532.

[0045] Further shown in **FIG. 5**, the sharing user 501 can post the encrypted share data 524, at their discretion, to social media 505 of their choosing. A receiving user 502, at their discretion, can upload the encrypted data 534 and use their device specific KEY₂ 516 to decrypt and view the share data. Advantageously, the cloud server 510 in this secure data sharing architecture does not require a customized data sharing website and the corresponding setup and site management burdens. Cloud server 510 overhead is limited to share list 540 management, data encryption and key generation and encrypted data and key distribution based upon an existing network of monitors 520, 530 with registered and readable device IDs 522, 532.

[0046] **FIG. 6** illustrates a real-time cloud computing architecture 600. On a user side 601, various physiological monitoring systems 610, 620 exist in perhaps widespread geographical locations and disparate environments. In contrast, a centralized cloud server 602 provides a variety of clinical services 660 for these monitoring systems 610, 620. In an embodiment, various users each possess a physiological monitoring system 610 having a sensor 611 and a corresponding monitor 615, such as described with respect to FIG. 1A, above. The sensor 611 generates an analog data stream 613 responsive to at least some aspect of the user's physiology. The monitor 615 receives and processes the analog data stream 613 and generates an digital encrypted data stream 617 responsive to the sensor 611. For example, the data stream 617 may be optical sensor data that has been filtered, digitized, amplified, demodulated and decimated in the monitor 615 and then encrypted and transmitted to the cloud server 602.

[0047] As shown in **FIG. 6**, in an embodiment, various other users each possess a physiological monitoring system 620 having a smart sensor 621 and a corresponding smart phone 625, such as described with respect to FIG. 1B, above. (A mobile or desktop computer 625 may be used in lieu of a smart phone). The smart sensor 621 generates an analog data stream 613 responsive to at least some aspect of a user's physiology. A monitor module integral to the smart sensor 621 receives and processes the analog data stream and generates a digital encrypted data stream 623 responsive to the analog data stream. The

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smart phone 625 receives the digital encrypted data stream 623 and transmits it directly to the cloud server 602.

[0048] Also shown in **FIG. 6**, clinical services performed in the cloud 602 include algorithm computations 662 and connectivity 664. Algorithms 662 include those for calculating SpO₂, SpHb, SpMet and SpCO; metabolic and lipid parameters; noninvasive blood glucose parameters; blood pressure parameters and other clinical, fitness and wellness-related parameters. Connectivity 664 includes dashboard, EMR and database, doctor and pharmacy connectivities. The cloud 602 returns encrypted measurement results 627 to the monitor 615 or the smart phone 625. The smart phone 625 passes the encrypted measurement results 623 to the smart sensor 621, and the smart sensor 621 sends the (decrypted) measurement results 623 back to the smart phone 625.

[0049] The advantages of real-time medical parameter computing via the cloud 602 is flexibility, scalability and ease of maintenance of the algorithm portfolio. In addition, the cloud offers significant IP protection for these algorithms because algorithms are not calculated within a device exposed to hands-on reverse engineering. The disadvantages are that medical parameter cloud computing requires highly reliable connectivity combined with patient risk mitigation if such connectivity is lost.

[0050] **FIG. 7** illustrates another real-time cloud-computing architecture 700. In particular, multiple sensors 711, 721 in conjunction with corresponding monitors 715, 725, such as described with respect to FIGS. 1A-B, above, provide clinical services 760 via real-time cloud computing. Clinical services 760 performed in the cloud include the calculation of one or more blood constituents and blood pressure. Blood constituent calculations include oxygen saturation, normal and abnormal hemoglobin, metabolic and lipid constituents and glucose, as described with respect to FIG. 6, above. Also as described with respect to FIG. 6, above, data flow for a sensor 711, 721 and connected monitor 715, 725 includes analog waveform data from the sensor 711, 721 to the connected monitor 715, 725; digital encrypted waveform data to the cloud 717,727, which returns encrypted measurement results 717,727 to the monitor 715, 725.

[0051] As shown in **FIG. 7**, clinical services 760 further include calculation of medical indices 770, each of which are combinations of physiological parameters. As such, two or more monitors 715, 725 independently generate encrypted

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waveform data 717, 727 used to derive a medical index 770. The cloud 760 time synchronizes this data accordingly. In an embodiment, each device has a master clock so as to record a universal time. The cloud server 702 corrects for time differences and delays among devices that are part of the same user account. As an example, a user acquires a smart sensor/smart phone 170 (FIG. 1B) and a cuff-based blood pressure monitor 180 (FIG. 1B). The user registers these devices via their cloud account. After that, when measurements are taken, the cloud server 702 verifies if the set of required parameters are available for a particular medical index 770 and if the parameters were measured within the required time frame for these parameters.

[0052] As an example, blood pressure constantly varies. Therefore, when calculating an index involving other parameters, any measurement time frame mismatch should be small (a few minutes). In contrast, total cholesterol changes very slowly, and therefore the measurement time frame mismatch with respect to other parameters can be much larger (hours). If any time frame mismatch between measured parameters for a particular medical index is within tolerance, the cloud server 702 processes and displays the index on at least one of the user's monitors 715, 725. If a time frame mismatch is too large, then each of the monitor 715, 725 displays are dashed out for that index.

[0053] **FIGS. 8A-F** illustrate medical indices 800 based upon trends in some or all of selected blood constituents, e.g. Hgb (hemoglobin), BUN (blood urea nitrogen) and Cr (creatinine); plethysmograph waveform features, e.g. plethysmograph variability index (PVI) and blood pressure (BP) that are indicative of dehydration 810, renal insufficiency 820, over-hydration 830, gastrointestinal bleeding 840, congestive heart failure exacerbation 850 and cardiovascular risk 860, respectively. Specifically, if a monitor and sensor are only capable of, or enabled to, measure blood constituent parameters, then a particular medical index ("index") may be based exclusively upon, say, Hgb, BUN and Cr. If a monitor and sensor are also capable of, or enabled to, measure plethysmograph waveform features, then that index may be based upon Hgb, BUN, Cr and PVI. (See, e.g. FIG. 1A). Further, if one or more monitors/sensors attach to a person, then that index may be based upon Hgb, BUN, Cr, PVI and BP. (See, e.g. FIG. 1B). A plethysmograph variability index (PVI) is described with respect to U.S. Pat. 8,414,499, filed 12/07/2007, titled "Plethysmograph Variability Processor"

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assigned to Masimo and incorporated in its entirety by reference herein. Note that PVI is not to be confused herein with a medical index although PVI may be used to calculate or otherwise indicate one or more medical indices.

[0054] As described herein, a medical index 800 is an indicator of the physiological status of a living being. Physiological status may be a positive condition, such as strength, endurance or conditioning, or a negative condition, such as a disease state or physiological weakness, to name a few examples. In an embodiment, a medical index ("index") has a binary value. That is, the index indicates a likelihood of the existence or nonexistence of a particular physiological status such as dehydration 810, renal insufficiency 820, over-hydration 830, gastrointestinal bleeding 840, CHF exacerbation 850 and cardiovascular risk 860, to name a few. In other embodiments, a medical index has a set of discrete values, such as a scale from 1 to 10. For example, 1 may indicate a very low likelihood and 10 a very high likelihood of a particular physiological status. In yet another embodiment, a medical index may have a continuous range of values, such as 0-100% so as to represent, for example, a probability that a particular medical condition exists.

[0055] As shown in **FIG. 8A**, dehydration 810 may be indicated from noninvasive measurements of Hgb, BUN and Cr, and in particular from rising values for each of these constituents over a predetermined time interval " Δt_{dh} ." If available, rising values of PVI over Δt_{dh} further indicate dehydration. If available, falling values of BP over Δt_{dh} further indicate dehydration.

[0056] As shown in **FIG. 8B**, renal insufficiency 820 may be indicated from noninvasive measurements of Hgb, BUN and Cr, and in particular from falling values of Hgb, relatively fast rising values of BUN and rising to relatively fast rising values of Cr over a predetermined time interval " Δt_{ri} ." If available, falling values of PVI over Δt_{ri} further indicate renal insufficiency. If available, falling values of BP over Δt_{ri} further indicate renal insufficiency.

[0057] As shown in **FIG. 8C**, over-hydration 830 may be indicated from noninvasive measurements of Hgb, BUN and Cr, and in particular from falling values of Hgb and BUN over a predetermined time interval " Δt_{oh} " and relatively constant values of Cr over Δt_{oh} . If available, falling values of PVI over Δt_{oh} further indicate over-hydration. If available, rising values of BP over Δt_{oh} further indicate over-hydration.

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[0058] As shown in **FIG. 8D**, gastrointestinal bleeding 840 may be indicated from noninvasive measurements of Hgb, BUN and Cr, and in particular from falling levels Hgb over a predetermined time interval " Δt_{gi} ." If available, rising values of PVI over Δt_{gi} further indicate gastrointestinal bleeding. If available, falling values of BP over Δt_{gi} further indicate gastrointestinal bleeding.

[0059] As shown in **FIG. 8E**, CHF exacerbation 850 may be indicated from noninvasive measurements of Hgb, BUN and Cr, and in particular from stable to falling levels of Hgb and BUN and stable to rising levels of Cr over a predetermined time interval " Δt_{chf} ." If available, falling values of PVI over Δt_{chf} further indicate CHF exacerbation. If available, relatively constant or rising values of BP over Δt_{chf} further indicate CHF exacerbation.

[0060] As shown in **FIG. 8F**, cardiovascular risk 860 may be indicated from noninvasive measurements of Chol, HDL, Chol/HDL and Trig and in particular from rising levels of Chol, Chol/HDL and Trig and falling levels of HDL over a predetermined time interval " Δt_{cvr} ." If available, rising values of BP over " Δt_{cvr} " further indicate cardiovascular risk.

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[0061] In an embodiment Δt_{xx} are the same for each index, i.e. $\Delta t_{dh} = \Delta t_{ri} = \Delta t_{oh} = \Delta t_{gi} = \Delta t_{chf} = \Delta t_{cv}$. In an embodiment, Δt_{xx} varies for each constituent of a particular index, e.g. $\Delta t_{xx}(\text{Hgb}) \neq \Delta t_{xx}(\text{BUN}) \neq \Delta t_{xx}(\text{Cr}) \neq \Delta t_{xx}(\text{PVI}) \neq \Delta t_{xx}(\text{BP})$. The order of the particular constituents for each index is not intended to indicate the relative weight of that constituent for determining a particular index. For example, the listing of Hgb first in tables 8A-E does not suggest Hgb is more indicative of determining a particular index than BUN, Cr, PVI or BP. In an embodiment, indices are calculated over a fixed Δt for one or more constituents. In an embodiment, indices are a function of a delta parameter value over a fixed Δt , e.g. $\Delta \text{BUN}/\Delta t$.

[0062] FIG. 9 illustrates trends in various physiological parameters, including blood-constituents, oxygen saturation, blood pressure, respiration rate (RR), temperature and heart-related parameters including heart rate (HR) and electrocardiogram (ECG) waveform features indicative of various physiological conditions, maladies and diseases. The use of one or more of these physiological parameters for determining a particular medical index depends on the availability of sensors, processors and algorithms for measuring these physiological parameters. Further, as noted above, the order of listing of various parameters in this table is not intended to indicate the relative sensitivity of a particular index to these parameters or the relative accuracy of determining a particular index utilizing these parameters.

[0063] Medical indices are described with respect to FIGS. 8-9, above, as based upon trends in various physiological parameters, i.e. changes in physiological parameters over time. This advantageously reduces the effect of individual variations in the baseline values for these physiological parameters, especially when the "normal" range for a particular physiological parameter is relatively broad. In other embodiments, however, medical indices may be based upon physiological parameter values in lieu of or in addition to physiological parameter trends, which advantageously allows a spot-check medical index calculation. As such, the up, sideways, and down arrows of FIGS. 8-9 can represent high (or very high), normal, and low (or very low) physiological parameter values so as to indicate a particular index.

[0064] In other embodiments, medical indices may be based upon fitness parameters derived, in part, from activity and location sensors, such as

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accelerometers and GPS devices, so as to measure, as examples, distance walked, calories burned, activity duration and intensity. These measurements may be combined with one or more of the parameters listed in FIG. 9 so as to derive medical indices indicative of exercise tolerance, cardiac function and arrhythmia analysis, to name a few.

[0065] A cloud-based physiological monitoring system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of this disclosure or any claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

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WHAT IS CLAIMED IS:

1. A cloud-based physiological monitoring system comprising:
 - a sensor in communications with a living being so as to generate a data stream generally responsive to a physiological condition of the living being;
 - a monitor that receives the data stream from the sensor and transmits the data stream to a cloud server;
 - the cloud server processes the data stream so as to derive a plurality of parameters having values responsive to the physiological condition;
 - the cloud server derives a medical index based upon a combination of the parameters;
 - the cloud server communicates the medical index to the physiological monitor; and
 - the physiological monitor displays the medical index.
2. The cloud-based physiological monitoring system according to claim 1 wherein:
 - the sensor comprises an optical sensor; and
 - the parameters comprise a blood constituent parameter.
3. The cloud-based physiological monitoring system according to claim 2 wherein the parameters further comprise a plethysmograph waveform parameter.

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4. The cloud-based physiological monitoring system according to claim 3 further comprising:

a blood pressure sensor in communications with the living being;

a blood pressure monitor that receives a blood pressure data stream from the blood pressure sensor and transmits the blood pressure data stream to the cloud server;

the cloud server processes the blood pressure data stream so as to derive a blood pressure parameter having a blood pressure value responsive to the physiological condition; and

the parameters further comprise the blood pressure parameter.

5. The cloud-based physiological monitoring system according to claim 4 wherein the medical index is based upon trends of the combination of the parameters.

6. The cloud-based physiological monitoring system according to claim 5 wherein:

the blood constituents include Hgb, BUN and Cr; and

the medical index relates to at least one of hydration, cardiovascular risk and renal insufficiency.

7. The cloud-based physiological monitoring system according to claim 5 wherein the medical index relates to at least one of dehydration, over hydration, gastrointestinal bleeding and congestive heart failure exacerbation.

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8. A cloud-based physiological monitoring method comprising:
generating sensor data generally responsive to a physiological phenomenon of a living being;
communicating the sensor data to a local medical device;
transmitting the sensor data from the local medical device to a remote cloud server;
processing the sensor data at the cloud server so as to derive a plurality of parameters having values responsive to the physiological phenomenon;
trending the parameters at the cloud server so as to derive a medical index responsive to the parameters, the medical index indicating a medical condition;
communicating the medical index to the local medical device; and
displaying the medical index on the local medical device.

9. The cloud-based physiological monitoring method according to claim 8 further comprising:
generating second sensor data generally responsive to a second physiological phenomenon of a living being;
communicating the second sensor data to a second local medical device;
transmitting the second sensor data from the second local medical device to the remote cloud server;
processing the second sensor data at the cloud server so as to derive a second parameter having values responsive to the second physiological phenomenon; and
trending the second parameter with at least one of the parameters at the cloud server so as to improve the efficacy of the medical index.

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10. The cloud-based physiological monitoring method according to claim 9 wherein generating sensor data comprises optically-deriving data responsive to pulsatile blood flow.

11. The cloud-based physiological monitoring method according to claim 10 wherein generating second sensor data comprises air-cuff-deriving data responsive to blood pressure.

12. The cloud-based physiological monitoring method according to claim 11 further comprising time frame matching the sensor data and the second sensor data at the cloud server.

13. The cloud-based physiological monitoring method according to claim 8 wherein displaying the medical index comprises indicating hydration on a smart cellular telephone.

14. A cloud-based physiological monitoring system comprising:
a physiological monitor in remote communications with a cloud server;
the physiological monitor inputs sensor data responsive to a physiological condition of a user;
the cloud server is in remote communications with the physiological monitor so as to upload the sensor data;
the cloud server executes signal processing algorithms so as to derive a physiological parameter from the sensor data;
the cloud server downloads the physiological parameter to the physiological monitor for display to user.

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15. The cloud-based physiological monitoring system according to claim 14 wherein the physiological monitor has an online application that executes if the cloud server is available and, if so, the online application:

- inputs sensor data from a physiological sensor in communications with the physiological monitor;
- transmits the sensor data to the cloud server;
- receives a parameter value that the cloud server derives from the sensor data; and
- displays the parameter value on the physiological monitor.

16. The cloud-based physiological monitoring system according to claim 15 wherein the physiological monitor has an offline application that executes if the cloud server is unavailable and, if so, the offline application:

- inputs sensor data from a physiological sensor in communications with the physiological monitor;
- calculates a parameter value from the sensor data; and
- displays the parameter value on the physiological monitor.

17. The cloud-based physiological monitoring system according to claim 14 wherein the online application performs an initial blood glucose calibration phase of the physiological monitor comprising:

- repeated blood sample data derived from a strip reader over an initial calibration period of several weeks; and
- repeated optical sensor data corresponding to the blood sample data;

the blood sample data and the sensor data transmitted to the cloud server;

and

the cloud server correlates the blood sample data and the sensor data during the initial calibration stage.

18. The cloud-based physiological monitoring system according to claim 17 wherein the online application further performs an end blood glucose calibration phase of the physiological monitor comprising:

- optical sensor data occasionally interspersed with blood sample data;

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the sensor data and occasional blood sample data transmitted to the cloud server; and

the cloud server updating the calibration as needed.

19. The cloud-based physiological monitoring system according to claim 14 wherein a share user establishes a receive user who is allowed to view the share user's medical information, the physiological monitoring system further comprising:

a share ID associated with the share user's physiological monitor;

a receive ID associated with the receive user's physiological monitor;

the cloud server associates the share ID with the receive ID; and

the cloud server encrypts the share user's medical information according to a share key based upon the share ID;

the cloud server generates a decryption key based upon the receive ID;

the cloud server transmits the encrypted medical information and share key to the share user; and

the cloud server transmits the receive key to the receive user.

20. The cloud-based physiological monitoring system according to claim 19 wherein:

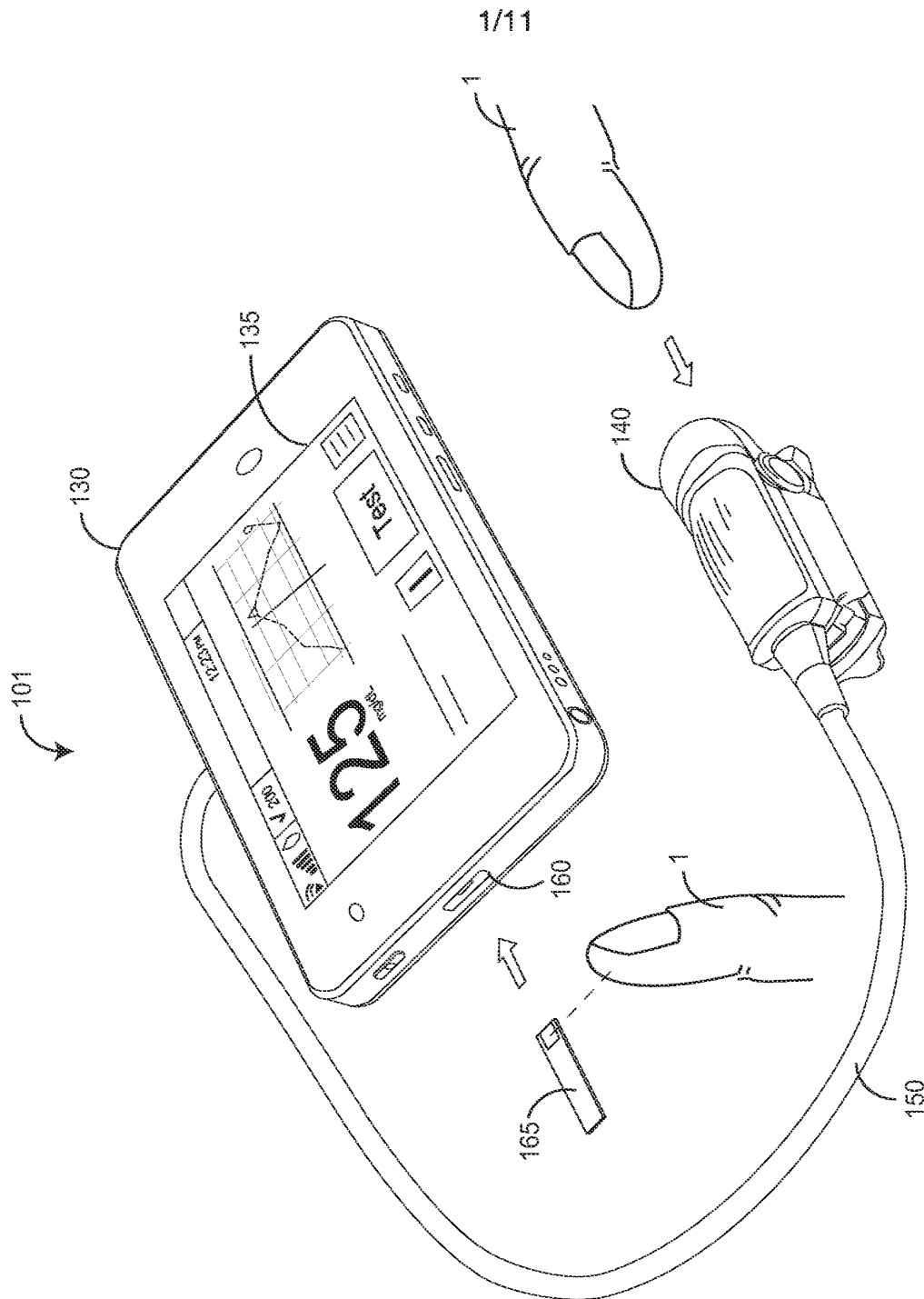
the share user posts the encrypted medical information to a public website;

the receive user downloads the encrypted medical information; and

the receive user decrypts the medical information using the receive key.

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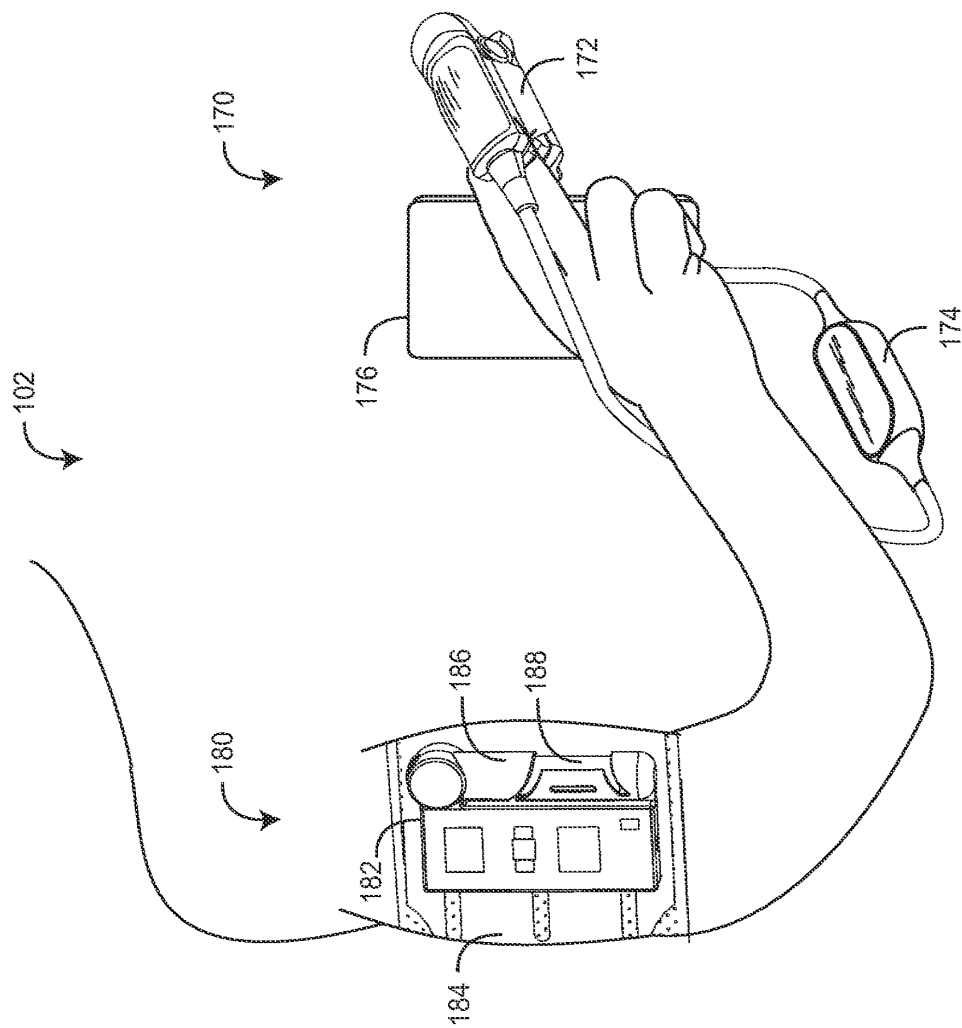


FIG. 1B

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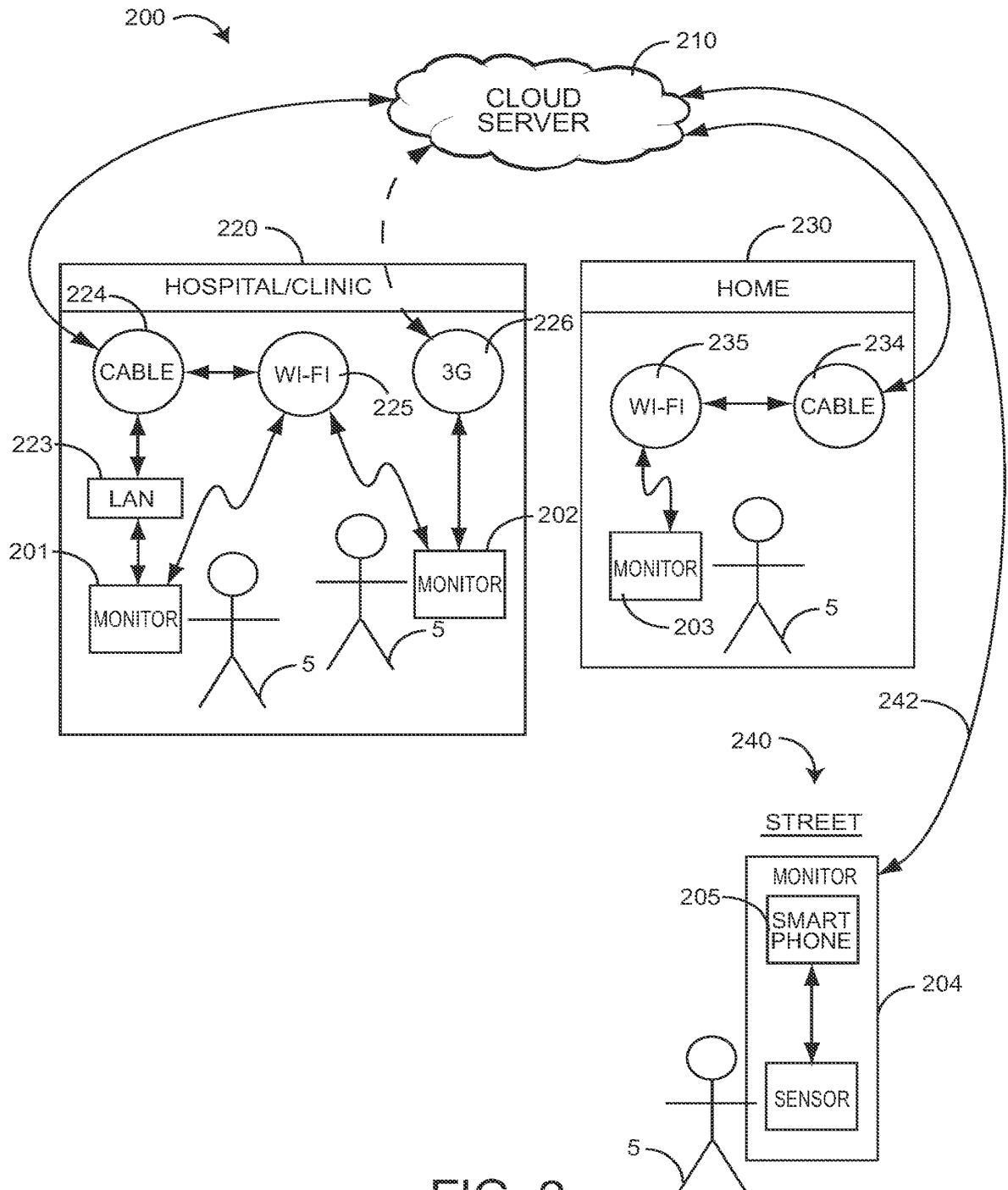
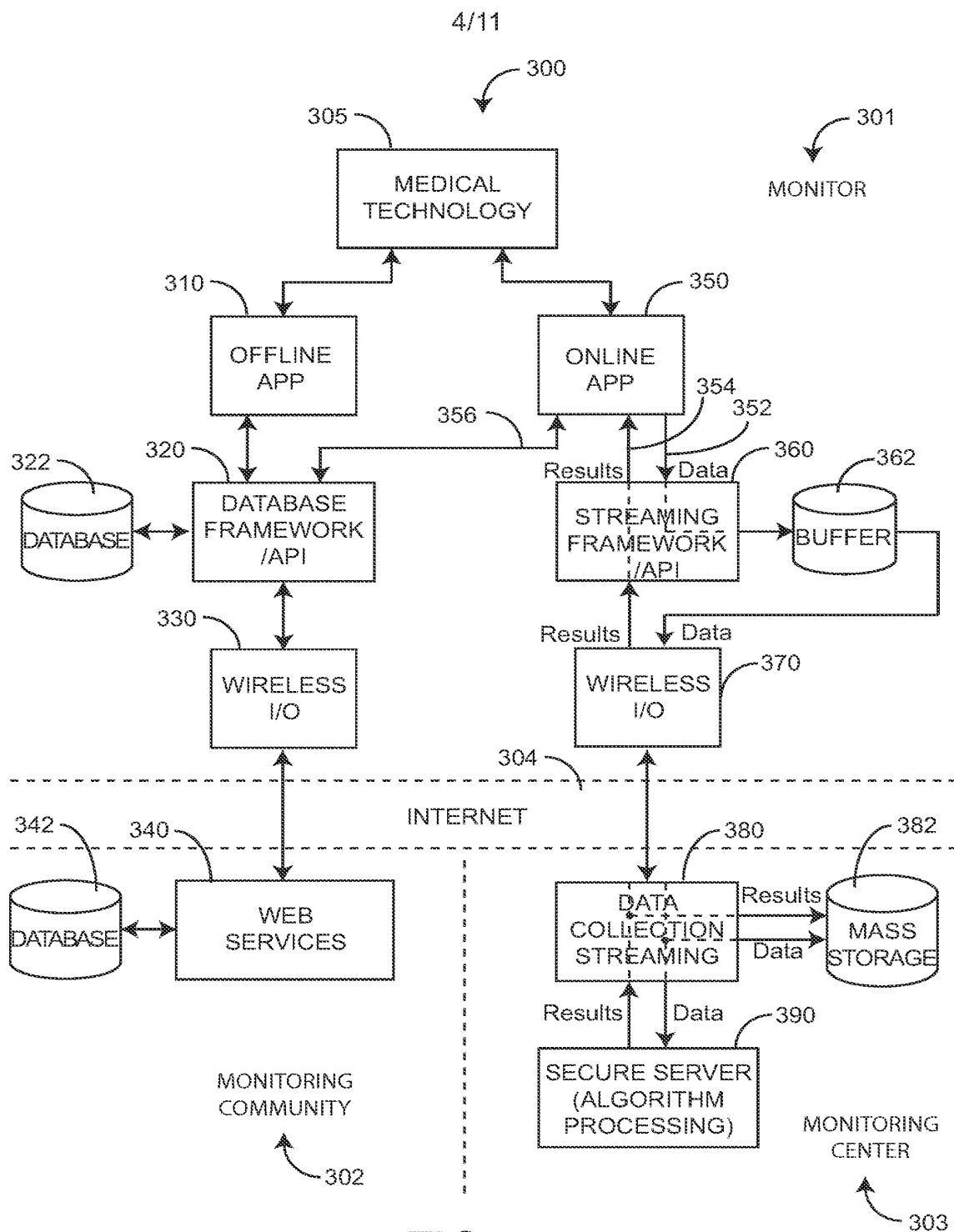


FIG. 2

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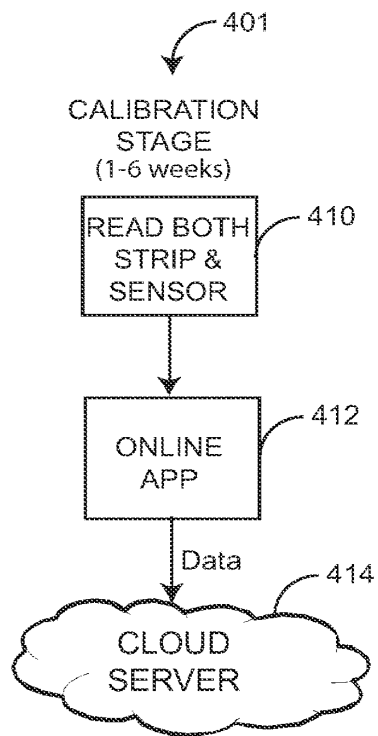


FIG. 4A

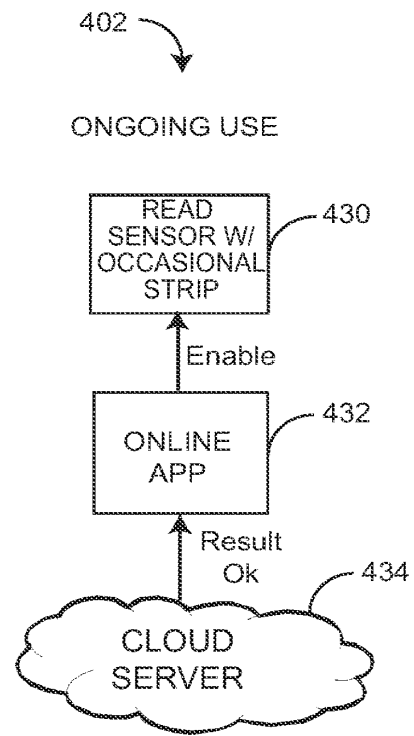


FIG. 4B

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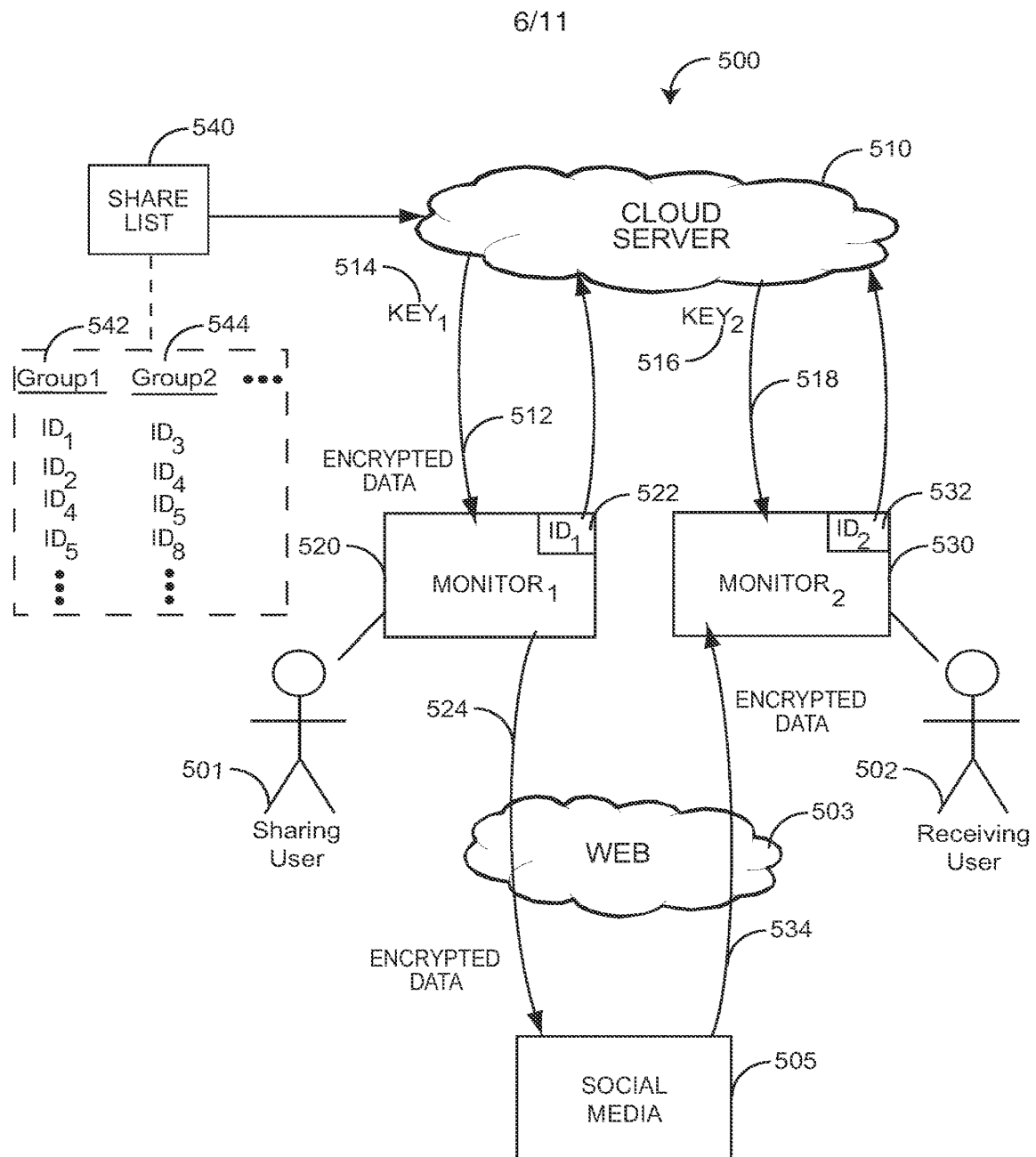


FIG. 5

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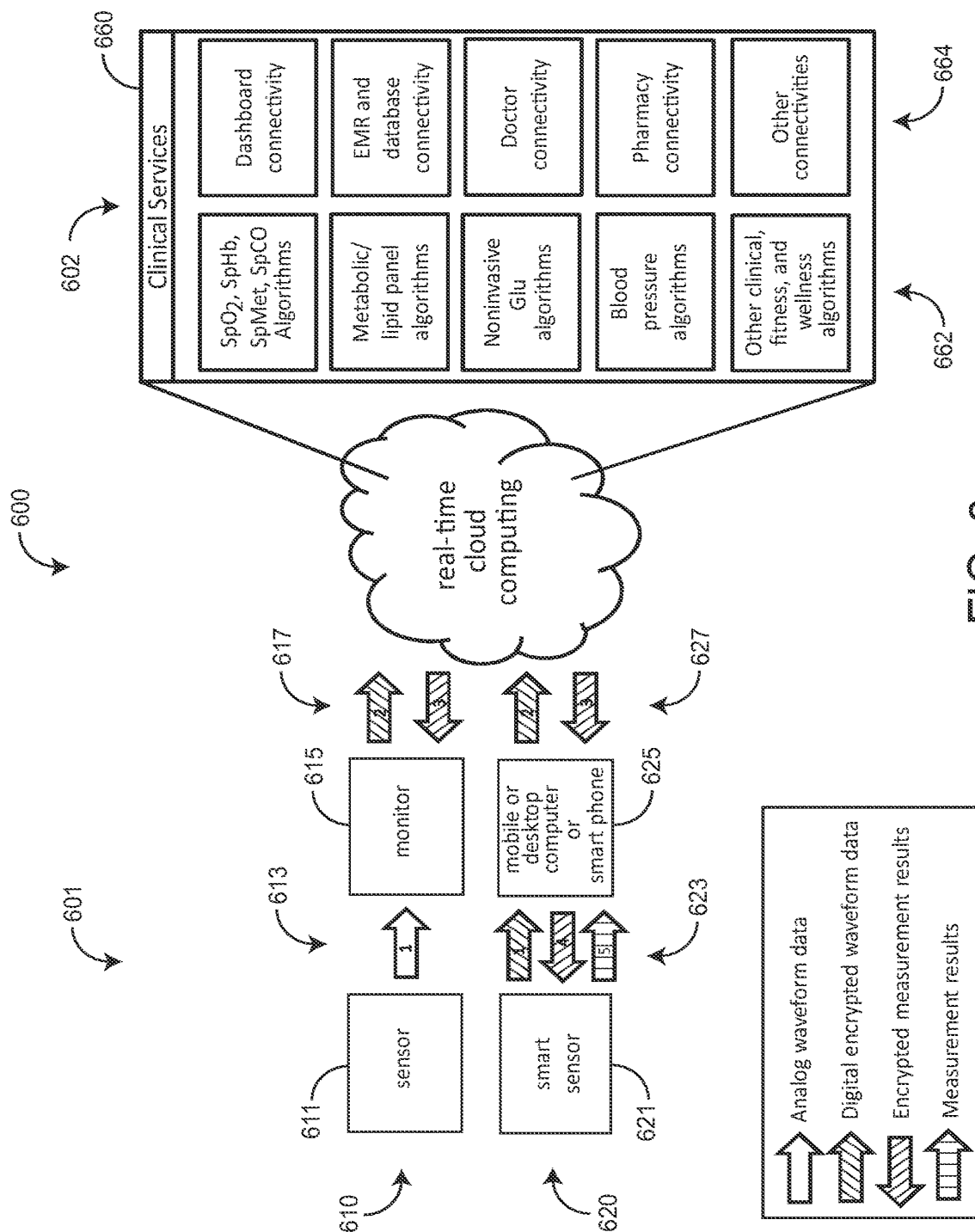
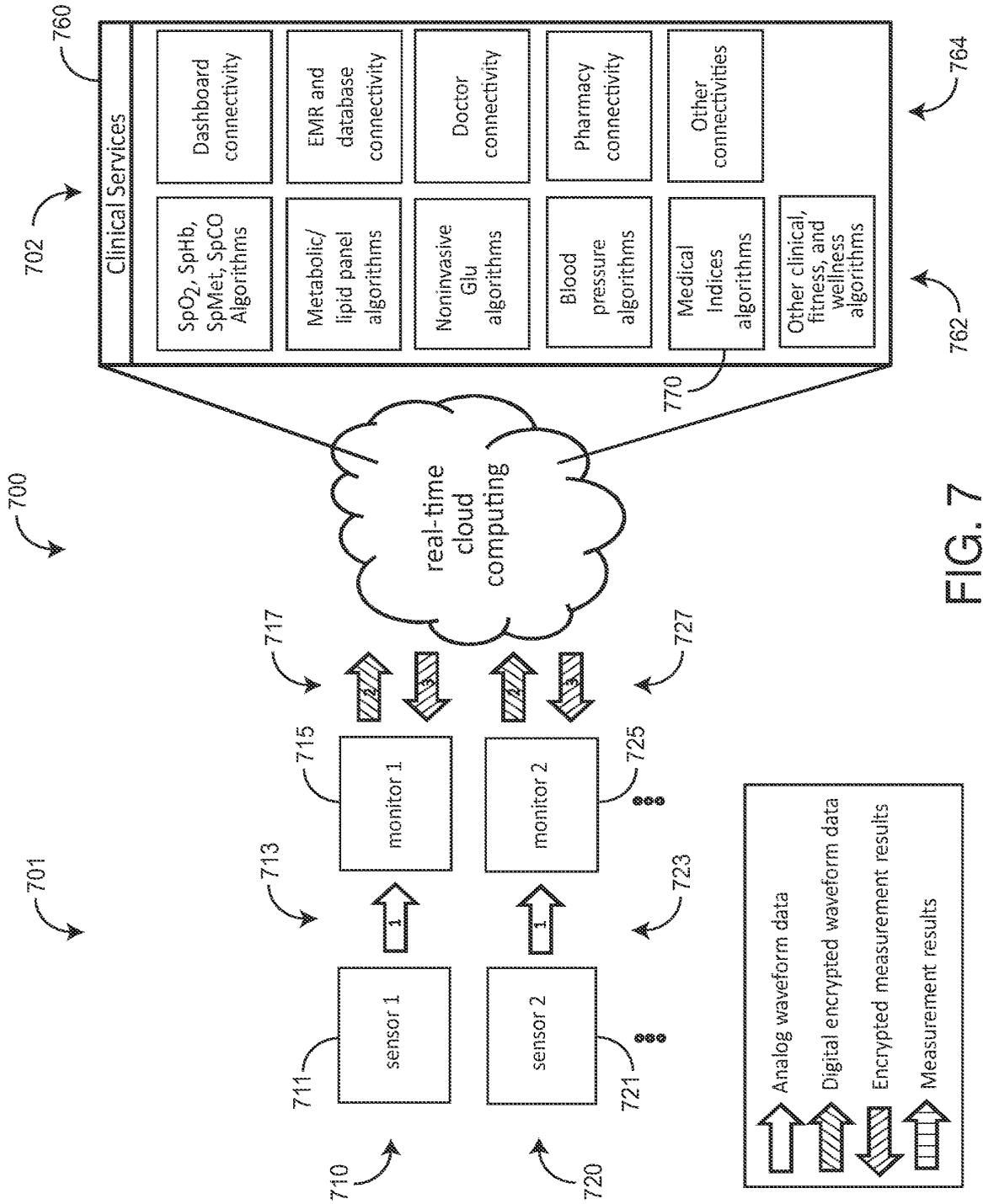


FIG. 6

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800

Index	Hgb	BUN	Cr	PVI	BP
Dehydration	↑	↑	↑	↑	↓

810

FIG. 8A

820

Index	Hgb	BUN	Cr	PVI	BP
Renal Insufficiency	↓	↑↑	↑ to ↑↑	↓	↑

FIG. 8B

830

Index	Hgb	BUN	Cr	PVI	BP
Over-hydration	↓	↓	↔	↓	↑

FIG. 8C

800

840					
Index	Hgb	BUN	Cr	PVI	BP
Gastrointestinal Bleeding	↓	↑	↔	↑	↔ to ↓

FIG. 8D

850

850					
Index	Hgb	BUN	Cr	PVI	BP
Congestive Heart Failure Exacerbation	↔ to ↓	↔ to ↓	↔ to ↑	↓	↔ to ↑

FIG. 8E

860

860					
Index	Chol	HDL	Chol/HDL	Trig	BP
Cardiovascular Risk	↑	↓	↑	↑	↑

FIG. 8F

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	Na+	K+	CO2	Cl-	Glu	Ca	BUN	Cre	ALP	ALT	AST	Tbil
<u>Index</u>												
Diabetic Ketoacidosis	↓	↕, mostly ↓	↓	↓	↑↑	↔ to ↓	↑	↑	↔	↔	↔	↔
Asthma Exacerbation	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔
Acute Upper Resp Infection	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔
Chronic Renal Insufficiency	↔ to ↓	↑	↓	↔ to ↓	↔ to ↑	↑	↑↑	↑↑	↔	↔	↔	↔
Liver Cirrhosis/Failure	↔ to ↓	↔	↔ to ↓	↔ to ↓	↔ to ↓	↔	↔ to ↓	↔ to ↑	↔ to ↑	↔	↔	↑
Chronic Hypertension	↔ to ↑	↔ to ↓	↔	↔	↔	↔	↔ to ↑	↔ to ↑	↔	↔	↔	↔
Hyperlipidemia	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔ to ↑	↔ to ↑	↔
Acute cholecystitis	↔	↔	↔	↔	↔	↔	↔	↔	↑	↔ to ↑	↔ to ↑	↑↑
Evolving MI	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔
Dehydration/heat stroke	↑	↔ to ↑	↑	↑	↔	↔	↑↑	↑	↔	↔ to ↑	↔ to ↑	↔ to ↑

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	Alb	TP	Chol	HDL	Trig	LDL	VLDL	SpO2	BP	RR	Temp	ECG/HR
↔	↔	↔	↔	↔	↑ or ↔	↔	↔	↔ to ↓	↓	↑	↓ or ↑	↑
↔	↔	↔	↔	↔	↔	↔	↔	↓	↔ to ↑	↑	↔	↑
↔	↔	↔	↔	↔	↔	↔	↔	↔ to ↓	↔	↑ or ↔	↑	↑ or ↔
↔	↔	↔	↔	↔	↔	↔	↔	↔	↑	↑ or ↔	↔	↔
↓	↔ to ↓	↓	↔ to ↓	↔ to ↓	↔ to ↓	↔ to ↓	↔ to ↓	↔ to ↓	↔ to ↓	↑ or ↔	↔	↔
↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔	↔
↔	↔	↔	↑	↔ to ↓	↑	↑	↑	↔	↔ to ↑	↔	↔	↔
↔	↔	↔	↔	↔	↔	↔	↔	↔	↔ to ↑	↔	↔	↔
↔	↔ to ↑	↔	↔ to ↑	↔ to ↓	↔ to ↑	↔ to ↓	↔ to ↓	↔ to ↓	↔ to ↓	↔ to ↑	↔ to ↑	↑, ST segment elevation, poor R wave progression
↑	↔	↑	↔	↔	↔	↔	↔	↔ to ↓	↓	↔ to ↑	↔ to ↑	↑

↔, may see peaked T waves
varied depending on extent of disease
LVH, possible evidence of old MI
↔, may see Q waves

FIG. 9

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/020903

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00 A61B5/0205
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G06F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 278 508 A1 (SHARP KK [JP]) 26 January 2011 (2011-01-26) paragraphs [0040], [0043] - [0048], [0055], [0069], [0076], [0079], [0080], [0188]	1-20
Y	----- WO 2012/099534 A2 (NITTO DENKO CORP [JP]; CHUA JULIANA [SG]; AUNG MYO MYINT [SG]; CHEAH X) 26 July 2012 (2012-07-26) page 9, line 21 - page 10, line 20 page 22, line 22 - line 27 page 27, line 6 - line 10 ----- -/--	1-20

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

2 May 2014

Date of mailing of the international search report

12/05/2014

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Authorized officer

Knüpling, Moritz

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INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	CHUNG-PING YOUNG ET AL: "A portable multi-channel behavioral state and physiological signal monitoring system", 2013 IEEE INTERNATIONAL INSTRUMENTATION AND MEASUREMENT TECHNOLOGY CONFERENCE (I2MTC), IEEE, 13 May 2012 (2012-05-13), pages 2687-2691, XP032451493, ISSN: 1091-5281, DOI: 10.1109/I2MTC.2012.6229401 ISBN: 978-1-4577-1773-4 page 2687 - page 2689	1-20
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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US 2011034209	A1	10-02-2011	NONE			

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(74) Agent: **ALTMAN, Daniel, E.**; Knobbe Marten Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

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[Continued on next page]

(54) Title: PATIENT MONITOR AS A MINIMALLY INVASIVE GLUCOMETER

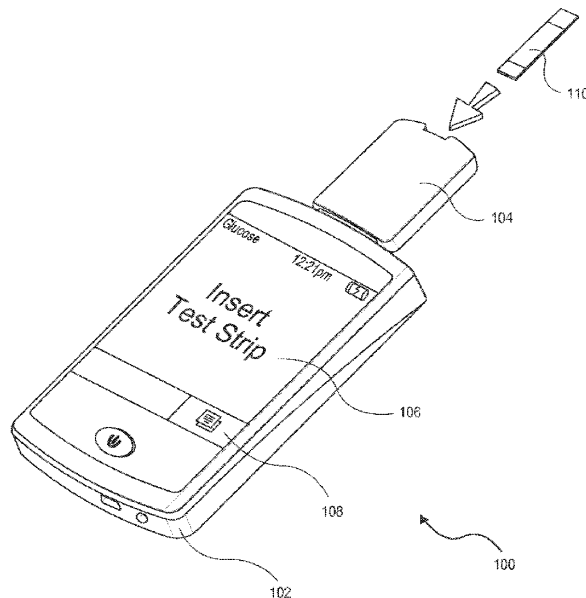


FIG. 1

(57) Abstract: In an embodiment, a patient monitor, such as a pulse oximeter, functions as a spot check glucometer when in communication with a blood glucose strip reader. In an embodiment, communications between the patient monitor and the strip reader may optionally be encrypted. Embodiments also include the strip reader housed in a dongle configured to mate with a sensor port of the pulse oximeter.

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**PATIENT MONITOR AS A MINIMALLY
INVASIVE GLUCOMETER**

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 61/782,923, filed March 14, 2013, the disclosure of which is hereby incorporated by reference herein in its entirety for all purposes.

BACKGROUND

[0002] The present application relates to the field of physiological monitoring devices. Specifically, the present application relates to the field of glucometers.

[0003] Health care providers have long recognized the need to monitor patients' analyte levels, including for example, oxygen saturation, carboxy hemoglobin, methemoglobin, total hemoglobin and glucose levels, as well as other physiological parameters, including for example, pulse rate, perfusion, hydration, overall wellness, pH, bilirubin, sepsis and others. Specifically, low blood glucose may lead to anxiety, weakness, and in extreme cases coma and death. Likewise, high blood glucose is associated with acidosis, diabetes, glucose spilling into the urine, polyurea, hemoconcentration and related stresses on organ systems, including the renal and cardiovascular systems. Glycemic control may be particularly important in the critical care setting, where high or low blood glucose has been related to increased morbidity and mortality, although many other uses are advantageous, including self blood sugar monitoring, fitness applications, and the like.

[0004] The standard of care in caregiver environments also includes patient monitoring through spectroscopic analysis using, for example, a pulse oximeter. Medical device manufacturers are continually increasing the processing capabilities of patient monitors, such as pulse oximeters, which process signals based on attenuation of light by patient tissue. In general, such patient monitoring systems include one or more optical sensors that irradiate tissue of a patient and one or more photodetectors that detect the radiation after attenuation thereof by

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the tissue. The sensor communicates the detected signal to a patient monitor, where the monitor often removes noise and preprocesses the signal. Advanced signal processors then perform time domain and/or frequency domain processing to determine measurements of blood constituents and other physiological parameters of the patient.

[0005] Manufacturers have advanced basic pulse oximeters that determine measurements for blood oxygen saturation ("SpO2"), pulse rate ("PR") and pethysmographic information, to read-through-motion oximeters, to co-oximeters that determine measurements of many constituents of circulating blood. For example, Masimo Corporation of Irvine California ("Masimo") manufactures pulse oximetry systems including Masimo SET® low noise optical sensors and read through motion pulse oximetry monitors for measuring SpO2, PR, perfusion index ("PI") and others. Masimo sensors include any of LNOP®, LNCS®, SofTouch™ and Blue™ adhesive or reusable sensors. Masimo oximetry monitors include any of Rad-8®, Rad-5®, Rad®-5v or SatShare® monitors.

[0006] Many innovations improving the measurement of blood constituents are described in at least U.S. Pat. Nos. 6,770,028; 6,658,276; 6,157,850; 6,002,952; 5,769,785 and 5,758,644, which are each incorporated by reference in their entirety herein for all purposes. Corresponding low noise optical sensors are disclosed in at least U.S. Pat. Nos. 6,985,764; 6,088,607; 5,782,757 and 5,638,818, which are each incorporated by reference in their entirety herein for all purposes.

[0007] Masimo also manufactures advanced co-oximeters including Masimo Rainbow® SET, which provides measurements in addition to SpO2, such as total hemoglobin (SpHb™), oxygen content (SpCO™), methemoglobin (SpMet®), carboxyhemoglobin (SpCO®) and PVI®. Advanced blood parameter sensors include Masimo Rainbow® adhesive, ReSposable™ and reusable sensors. Masimo's advanced blood parameter monitors include Masimo Radical-7™, Rad-87™, and Rad-57™ monitors as well as Pronto and Pronto-7 spot check monitors.

[0008] Many innovations relating to the foregoing technologies are described in at least U.S. Pat. Nos. 7,647,083; 7,729,733; U.S. Pat. Pub. Nos.

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2006/0211925; and 2006/0238358, which are each incorporated by reference in their entirety herein for all purposes.

[0009] These and other instruments have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY

[0010] In an embodiment, a patient monitor, such as a pulse oximeter, co-oximeter, or other patient monitor ("patient monitor"), functions as a glucometer when in communication with a blood glucose strip reader. In various embodiments, communications between the patient monitor and the strip reader may optionally be encrypted, may implement authorization and/or authentication protocols or the like, or may implement quality control by providing authorized strip readers to communicate with the monitor.

[0011] In an embodiment, a spot check monitoring system using a monitor configured to accept signals responsive to light attenuated by body tissue is disclosed which comprises: a minimally invasive glucose reader; and a patient monitor in communication with said minimally invasive glucose reader, wherein, when a glucose level is read by said minimally invasive glucose reader, said glucose level is transmitted to said patient monitor, wherein said patient monitor is configurable as an oximeter and is configurable to display said glucose level when said glucose level is transmitted to said patient monitor.

[0012] According to an aspect, the spot check monitoring system may further comprise a dongle, wherein said dongle houses said minimally invasive glucose reader.

[0013] According to another aspect, the spot check monitoring system may further comprise a reader board, wherein said minimally invasive glucose reader is mounted on said reader board.

[0014] According to yet another aspect, the spot check monitoring system may further comprise an encryption controller configured to encrypt information from said minimally invasive glucose reader.

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[0015] According to another aspect, the spot check monitoring system may further comprise an encryption board, wherein said encryption controller is mounted on said encryption board.

[0016] According to yet another aspect, said encryption board and said reader board may be different boards.

[0017] According to another aspect, the spot check monitoring system may further comprise strips configured to be read by said minimally invasive glucose reader, wherein said strips comprise source identifying strips.

[0018] According to yet another aspect, when said patient monitor is configured as said oximeter, said patient monitor communicates with an optical sensor that outputs signals responsive to light attenuated by patient tissue carrying pulsing blood, said patient monitor receiving said signals and configured to process said signals to determine physiological parameters including at least an indication of oxygen saturation of the patient tissue.

[0019] In another embodiment, a method of converting a patient monitor to a spot check glucometer is disclosed which comprises providing a minimally invasive glucose reader configured to accept strips carrying samples to be analyzed; providing a patient monitor configured to communicate with an optical sensor to receive signals responsive to light attenuated by tissue of a patient carrying pulsing blood, to process said signals, to determine one or more measurements of physiological parameters of said patient including at least oxygen saturation; associating said reader with said patient monitor causing said patient monitor to change to a spot check glucometer; inserting one of said strips into said reader; and displaying on a display of said patient monitor measurement data responsive to said sample on said inserted strip.

[0020] According to an aspect, said associating comprises establishing electrical communication between said reader and said patient monitor.

[0021] According to another aspect, said establishing electrical communication comprises attaching a dongle housing said reader.

[0022] According to yet another aspect, said establishing electrical communication comprises establishing encrypted communication with said monitor.

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[0023] According to another aspect, establishing electrical communication comprises establishing communication through an encryption board.

[0024] In yet another embodiment, an encrypted source-identifying glucose strip reader configured to change an oximeter into a glucometer is disclosed which comprises a strip reader configured to accept samples on a strip and output a signal responsive to characteristics of said sample, said characteristics including a measure of glucose in said sample; a controller communicating with said strip reader to determine said measure of glucose from said sample and output data indicative of at least said measure; and an encryption controller configured to receive said data from said controller and output encrypted data to an oximeter configured to modify its operation to present display indicia to a user of the oximeter, the display indicia responsive to said measure of said glucose in said sample, the encrypted data identifying by its encryption the source of the reader.

[0025] According to an aspect, the reader may further comprise a reader board, wherein said strip reader and said controller are mounted on said reader board.

[0026] According to another aspect, the reader may further comprise an encryption board, wherein said encryption controller is mounted on said encryption board.

[0027] According to yet another aspect, said strip reader and said controller are mounted on said encryption board.

[0028] According to another aspect, the reader may further comprise a dongle, wherein the strip reader, the controller and the encryption controller are housed within a dongle.

[0029] According to yet another aspect, said dongle comprises a connector, said connector having a mechanical and pin layout that mechanically mates with an oximeter connector normally connected to a noninvasive optical sensor.

[0030] According to another aspect, said strip reader and said controller comprises an OEM strip reader and controller.

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[0031] For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the disclosure have been described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the disclosure. Thus, the disclosures disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] The following drawings and the associated descriptions are provided to illustrate embodiments of the present disclosure and do not limit the scope of the claims.

[0033] FIG. 1 illustrates an embodiment of a minimally invasive glucometer system.

[0034] FIG. 2A illustrates a simplified block diagram of an embodiment of a minimally invasive glucometer.

[0035] FIG. 2B illustrates an exploded view of an embodiment of a reader dongle that may be used with the minimally invasive glucometer.

[0036] FIG. 2C illustrates a perspective view of an embodiment of the reader dongle of FIG. 2B that may be used in a minimally invasive glucometer.

[0037] FIG. 3 illustrates a simplified configuration process of an embodiment of a minimally invasive glucometer.

[0038] FIGS. 4A-4T illustrate exemplary user interfaces of a minimally invasive glucometer according to various embodiments of the present disclosure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0039] The present disclosure includes a pulse oximeter or other patient monitor as a minimally invasive glucometer. In an embodiment, a glucose strip reader is connected to, and/or in communication with, a pulse oximeter. The pulse oximeter is configured so that it acts as a minimally invasive glucometer when connected to the glucose strip reader, displaying glucose measurements to a user. For example, the user may first connect the strip reader to the pulse oximeter. Then, the user may insert a glucose strip in the strip reader. Next, the

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user may place a sample of their blood on the strip. The strip reader may then measure the glucose level of the user's blood and pass this information to the pulse oximeter. The pulse oximeter may then display the glucose level on the pulse oximeter display so that it may be read by the user. Thus, advantageously, according to various embodiments, the pulse oximeter or other patient monitor, when paired with the glucose strip reader, may additionally be used as a minimally invasive glucometer, among other things.

[0040] In an embodiment, communications between the glucose strip reader and the pulse oximeter or other patient monitor are encrypted. For example, the glucose strip reader may be authorized and/or authenticated to communicate with the pulse oximeter or other patient monitor.

[0041] To facilitate a complete understanding of the disclosure, the remainder of the detailed description describes the disclosure with reference to the drawings, wherein like reference numbers are referenced with like numerals throughout. The terminology used in the description presented herein is not intended to be interpreted in any limited or restrictive manner, simply because it is being utilized in conjunction with a detailed description of certain specific embodiments of the disclosure. Furthermore, embodiments of the disclosure may include several novel features, no single one of which is solely responsible for its desirable attributes or which is essential to practicing the embodiments of the disclosure herein described.

[0042] FIG. 1 illustrates a minimally invasive glucometer system 100 according to an embodiment of the present disclosure, including a patient monitor 102 and a reader dongle 104. The system 100 interacts with disposable glucose strips 110, which in some embodiments, include source identifying strips and/or source identifying technology interacting with said dongle 104, and in other embodiments include straightforward commercially available disposable strips. Source identifying technology may advantageously include a chemical(s) recognizable by the reader and/or that cause the reader to generate output data recognizable by communicating processor. Other source identifying technology includes an electrical connection that reads, for example, a memory and/or electrical property of the strips 110, and/or RFID or other wireless based communication with the strip. Still other source identifying technology may include

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devices and/or chemicals associated with said strip that produce a recognizable signal when optically read by monitor 102. An artisan will recognize from the disclosure herein a number of technologies, protocols, and interactions that may provide source identification of the strips 110.

[0043] The patient monitor 102 comprises a display 106 and control buttons 108. Advantageously, in certain embodiments, the minimally invasive glucometer system 100 can have a shape and size that allows a user to operate it with a single hand, or attach it, for example, to a sleeve and/or other attachment mechanism proximate a patient's body or limb.

[0044] In the minimally invasive glucometer system 100, the patient monitor 102 may be connected to, and communicate with, the reader dongle 104. The patient monitor 102 may also communicate with the display 106 and the control buttons 108. Generally, blood or other solution is presented on the disposable glucose strip 110, and sample is inserted into reader dongle 104 where it is read by a reader designed to interact with the strip 110 (now carrying the sample).

[0045] In various embodiments, the user interacts with the minimally invasive glucometer system 100 to obtain spot check glucose measurements. As explained in more detail below with reference to FIGS. 2A-C and 3, in various embodiments the user inserts the disposable glucose strip 110 into the reader dongle 104, and then places a blood sample on the disposable glucose strip 110. The minimally invasive glucometer system 100 may then display glucose measurements obtained from reader dongle 104. Advantageously, the patient monitor 102 may be used, according to various embodiments, as a minimally invasive glucometer as it displays glucose measurements obtained from the reader dongle 104.

[0046] In an embodiment, the patient monitor 102 comprises a commercial available monitor from, for example, Masimo Corporation. For example, the patient monitor 102 may comprise any of Rad-8®, Rad-5®, Rad@-5v, SatShare®, Radical-7™, Rad-87™, Rad-57™ monitors, or Pronto or Pronto-7 spot check monitors.

[0047] FIG. 2A illustrates a simplified exemplary block diagram of an embodiment of the minimally invasive glucometer system 100 described above

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with reference to FIG. 1. According to an embodiment, the minimally invasive glucometer system 100 includes the reader dongle 104, the patient monitor 102, and an optionally encrypted communications link 222. The reader dongle 104 may include a strip reader printed circuit board (PCB) 210 and an optional encryption PCB 220 (also referred to as an encryption board). Additionally, the strip reader PCB 210 (also referred to as a reader board) may include a reader 212 and a controller 214. The patient monitor 102 may include a front-end interface 230, a signal processor 240, a user interface processor 242, a display 243, a storage 244, a network interface 246, and/or an optional memory 248. The front-end interface 230 may further include an optional decryption chip 232. In an embodiment, the optional encryption PCB 220 includes an encryption chip, an encryption controller, and/or an encryption microcontroller (as described below in referenced to FIG. 2B). Other embodiments may include other arrangements of the hardware components, one or more other boards, flexible circuits, and/or the like, or even be incorporated into one or more controllers, microprocessors or the like, and are still within the scope of the present disclosure. For example, in an embodiment, each of the controller 214, the reader 212, and an encryption controller may be mounted on the same board.

[0048] In the minimally invasive glucometer system 100, the strip reader PCB 210 may include the reader 212 and the controller 214 in communication with each other. Further, the strip reader PCB 210 and the optional encryption PCB 220 of the reader dongle 104 may be in communication with each other. The optional encryption PCB 220 of the reader dongle 104 may be in communication with the front-end interface 230 of the patient monitor 102. Communications from the optional encryption PCB 220 and the front-end interface 230 may occur over the optionally encrypted communications link 222. The front-end interface 230 may contain the optional decryption chip 232, and may be in communication with the optional decryption chip 232. Within the patient monitor 102, the front-end interface 230 may be in communication with the signal processor 240, which may be in communication with the user interface processor 242, the storage 244 and/or the network interface 246. Further, the optional memory 248 may be in communication with the front-end interface 230 and the signal processor 240, and the user interface processor 242 may be in communication with the display 243.

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[0049] In operation, according to an embodiment the disposable glucose strip 110 is inserted into strip reader PCB 210, and read by reader 212. Minimally invasive glucose measurements (also referred to as glucose level(s)) may be obtained from the disposable glucose strip 110 by controller 214. Glucose measurement data may then be forwarded by strip reader PCB 210 to the optional encryption PCB 220. The optional encryption PCB 220 may encrypt the minimally invasive glucose measurement data so that they may then be communicated to the patient monitor 102. The encrypted glucose measurement data may then be transmitted to the front-end interface 230 over the optionally encrypted communications link 222. Communications over the optionally encrypted communications link 222 may be through wired and/or wireless connections, and may use any suitable communications protocol. For example, communication may be serial or parallel, through Universal Serial Bus (USB) (wired or wireless), Ethernet, Bluetooth, Near Field Communications (NFC), radio frequency (RF), infrared, and/or WiFi (such as any 802.1x interface), among others as is known in the art. In an embodiment, the strip reader PCB 210 may be referred to as a minimally invasive glucose reader. In another embodiment, the reader 212 may be referred to as a minimally invasive glucose reader.

[0050] [0038] According to an embodiment the front-end interface 230 provides an interface that decrypts and adapts the output of the optional encryption PCB 220. For example, in an embodiment, the optional decryption chip 232 decrypts the glucose measurement data transmitted to the front-end interface 230 so that the data may be processed by signal processor 240. Advantageously, the optional encryption PCB 220 and the optional decryption chip 232 may allow for encrypted communications to ensure that the reader dongle 104 is compatible with, and authorized for use with, the patient monitor 102. In an embodiment, the optional decryption chip 232 prevents communication with the reader dongle 104 until the optional encryption PCB 220 is authenticated as having the proper credentials to communicate with the patient monitor 102. The optional encryption PCB 220 and the optional decryption chip 232 may implement any suitable cryptographic system, for example public/private key, among others. In an alternative embodiment, the minimally invasive glucometer system 100 does not include the optional encryption PCB 220 and the optional decryption chip 232. In this embodiment, the strip reader PCB 210 may

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communicate directly with the front-end interface 230, and the optionally encrypted communications link 222 may transmit unencrypted data.

[0051] The decrypted glucose measurement data may then be transmitted to the signal processor 240. In an embodiment, the signal processor 240 may include processing logic that determines measurements for desired analytes, such as glucose, based on the signals received from the reader dongle 104. The signal processor 240 may be implemented using one or more microprocessors or subprocessors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and/or the like.

[0052] The signal processor 240 may provide various signals that control the operation of strip reader PCB 210. For example, the signal processor 240 may provide signals to reset the strip reader PCB 210, and/or direct the strip reader PCB 210 to begin reading and transmitting glucose measurement data. As also shown, an optional memory 248 may be included in the front-end interface 230 and/or in the signal processor 240. This optional memory 248 may serve as a buffer and/or storage location for the front-end interface 230 and/or in the signal processor 240, among other uses. Moreover, the monitor 102 may power one or more of the PCBs 210, 220.

[0053] The user interface processor 242 may provide an output, for example the display 106 (see also FIG. 1), for presentation to the user of the minimally invasive glucometer system 100. The user interface processor 242 may be implemented to include and/or communicate with a touch-screen display, an LCD display, an organic LED display, or the like. The signal processor 240 may transmit minimally invasive glucose measurement information to the user interface processor 242 such that the information may then be displayed on the display 106, which may then be observed by the user. Additionally, the user may provide inputs to the user interface processor 242 through, for example, the control buttons 108 on the display 106. User inputs may be processed by the user interface processor 242 and then transmitted to the signal processor 240, where they may be processed and may, for example, control the reader dongle 104. For example, the user may turn the reader dongle 104 and/or the patient monitor 102 on and off. Alternatively, as another example, the user may use the

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control buttons 108 to direct the strip reader PCB 210 to read the disposable glucose strip 110 and transmit the minimally invasive glucose measurements to the signal processor 240, and subsequently to the display 106 where they may be observed by the user.

[0054] The storage 244 and the network interface 246 represent other optional output connections that may be included in the patient monitor 102. The storage 244 may include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications may be stored in the storage 244, which may be executed by the signal processor 240 and/or another processor of the patient monitor 102. The network interface 246 may be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (for example, WiFi such as any 802.1x interface, including an internal wireless card), and/or other suitable communication device(s) that allows the patient monitor 102 to communicate and share data with other devices. The patient monitor 102 may also include various other components not shown, such as a microprocessor, graphics processor, and/or controller to output to the user interface processor 242, to control data communications, to compute data trending, and/or to perform other operations. Alternatively, the patient monitor 102 may not include the user interface processor 242, but may communicate user interface data directly between the signal processor 240 and the display 106.

[0055] In an embodiment, the strip reader PCB 210 comprises a commercially available OEM strip reader from, for example, Nova Medical, or others. In an embodiment, the strip reader PCB 210 comprises a prick reader that operates by pricking the user's fingertip or other area of their body to obtain a blood sample to be analyzed. In this embodiment, the disposable glucose strip 110 may not be necessary for operation of the minimally invasive glucometer system 100.

[0056] In an embodiment, the optional encryption PCB 220 may be packaged together with the strip reader PCB 210 in the reader dongle 104. Alternatively, the optional encryption PCB 220 may be packaged separately, and may include an external connection for communication with the strip reader PCB 210 and the patient monitor 102. In another alternative, strip reader PCB

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210 communicates wirelessly (such as through WiFi or other suitable communications protocol) with the optional encryption PCB 220 and/or the patient monitor 102.

[0057] In an embodiment, the optional encryption PCB 220 may not be a PCB, but may be embodied in a separate chip, ASIC, FPGA, or the like, or may alternatively be integrated with the strip reader PCB 210. Alternatively, the functionality of the optional encryption PCB 220 may be accomplished in a software application running on a multipurpose processor.

[0058] Alternatively, as mentioned above, in an embodiment the minimally invasive glucometer system 100 may not include the optional encryption PCB 220 and the optional decryption chip 232, so that communications between the strip reader PCB 210 and the patient monitor 102 do not include encryption and decryption of glucose measurement data. In this embodiment, the reader dongle 104 comprises the strip reader PCB 210.

[0059] The strip reader PCB 210 may also be referred to as a strip reader, a glucose reader, a minimally invasive glucose reader, and/or a blood glucose reader, among other things. Thus, in embodiments in which the optional encryption PCB 220 is not included in the reader dongle 104, references a reader dongle, strip reader, glucose reader, minimally invasive glucose reader, and/or blood glucose reader may be understood to reference the strip reader PCB 210. Additionally, it is to be understood that in some embodiments the reader dongle 104 may or may not include the optional encryption PCB 220. Thus in some embodiments references to the reader dongle 104 may or may not include the optional encryption PCB 220.

[0060] In further embodiments, the monitor 102 receives a signal that the PCB 210 (and optionally, PCB 220) is present, thereby allowing the monitor 102 to change programming from an oximeter to programming as disclosed herein. In an embodiment, the mechanical connection of the PCB 210 (and optionally, PCB 220) signals the monitor 102 that it is to configure itself as a minimally invasive glucometer. In other embodiments, receipt of communication from the PCB 210 (and optionally, PCB 220) signals the monitor 102 that it is to configure itself as a minimally invasive glucometer. In still other embodiments, the monitor 102 is configured to determine that it is not receiving optical data from a

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non-invasive optical sensor, but is receiving other data, and one possible source of the other data is the PCB 210 (and optionally, PCB 220), and therefore, upon detecting said other data, the monitor 102 configures itself as a minimally invasive glucometer. In other embodiments, the PCB 210 (and optionally, PCB 220) includes some or all of the software needed to execute a minimally invasive glucometer and the monitor 102 receives this software and then executes its processes to implement said glucometer functions.

[0061] Although disclosed with reference to the specific embodiments of FIGS. 1 and 2, an artisan will recognize from the disclosure herein other hardware and/or software configurations for accomplishing the desired functionality, including, for example, custom semiconductors, controllers, processors, or the like for performing individual or sets of functions.

[0062] FIG. 2B illustrates an exploded view of an embodiment of the reader dongle 104 that may be used with the minimally invasive glucometer. Further, FIG. 2C illustrates a perspective view of an embodiment of the fully assembled reader dongle 104 of FIG. 2B.

[0063] The embodiment of the reader dongle 104 shown in FIGS. 2B and 2C includes a housing 260, a connector housing 262, the strip reader PCB 210 (as described in reference to FIG. 2A), and the optional encryption PCB 220 (as described in reference to FIG. 2A). Further, as described with reference to FIG. 2A above, the strip reader PCB 210 includes the strip reader 212, and the controller 214. Also shown in FIG. 2B is a flex circuit 264 which may be used to connect the strip reader PCB 210 to the optional encryption PCB 220. The optional encryption PCB 220 also includes the optional memory 248 (as described above in reference to FIG. 2A), and an encryption microcontroller 266.

[0064] In operation, according to various embodiments and as described above with reference to FIG. 2A, the strip reader PCB 210 communicates measurements to the optional encryption PCB 220 through the flex circuit 264. The flex circuit 264 may act as a connector to enable communications between the two PCBs. Once measurements are communicated to the optional encryption PCB 220, the encryption microcontroller 266 may, as described above, encrypt the data, thus enabling encrypted communication with the patient monitor 102. In various embodiments, the encryption microcontroller

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266 may comprise an encryption chip, an encryption controller, an encryption microcontroller, and/or any combination of encryption chips, controllers, and microcontrollers. In an embodiment, the strip reader PCB 210 cannot communicate with the patient monitor 102 directly, as the strip reader PCB 210 lacks devices or modules to encrypt the communications. Thus, the encryption microcontroller 266 may encrypt communications originating with the reader dongle 104 and transmitting to the front-end interface 230 of the patient monitor 102. Thus, in an embodiment, only the optional encryption PCB 220 may communicate with the patient monitor 102 via encrypted communications. The encryption microcontroller 226 advantageously provides, according to various embodiments, quality control by limiting the type and suppliers of strip reader technology that can communicate with a specific manufacture's instruments, such as, for example, the monitor 102. Quality control may be advantageous as the instrument manufacturer is aware of tolerances, accuracies, requirements, and/or other characteristics often used during technology development and deployment to consumers and/or caregivers.

[0065] In the reader dongle 104 of the embodiments of FIGS. 2B and 2C, the connector housing 262 houses an electrical connector that may be coupled to the patient monitor 102, as shown in FIG. 1. The connector type of the connector housing 262 may include any suitable connector for allowing communications between the reader dongle 104 and the patient monitor 102. In an embodiment, the connector housing 262 may securely couple the reader dongle 104 to the patient monitor 102 such that the two are affixed or coupled to one another. In an embodiment, the connector housing 262 may comprise a flexible connection and/or a hinged connection. In an embodiment, the reader dongle 104 does not include a connector housing 262, but rather communications between the reader dongle 104 and the patient monitor 102 are wirelessly transmitted. In still other embodiments, a flexible circuit and/or cable could extend between the dongle 104 and the connector end thereof allowing placement of the dongle in a convenient location. Other embodiments may also include a mechanical latch and/or catch to securely hold the housing 262 or at least the connector portion thereof to the monitor 102. Some embodiments, may include a mechanical and pin layout that mechanically mates the connector housing 262 with the pulse oximeter 102.

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[0066] FIG. 3 illustrates an example simplified configuration process of an embodiment of a minimally invasive glucometer. In various embodiments the configuration process may include more or fewer blocks, and/or the blocks may be arranged in a different order. The exemplary configuration process begins at block 302 wherein a patient monitor, such as the patient monitor 102, is provided. Next, in block 304, a strip reader dongle, such as the reader dongle 104, is provided.

[0067] Then, in optional block 306, the strip reader dongle is connected to the patient monitor 102 through a sensor connection. The sensor connection is typically associated with a sensor connector for an optical sensor used in oximetry and known to an artisan from the disclosure herein. Once connected, the data can be transmitted between the strip reader dongle 104 and the patient monitor 102. The sensor connection may be, for example, a port, plug, and/or jack on the side of the patient monitor. In an embodiment, the strip reader dongle is a single self-contained unit that may be physically and securely attached to the sensor connection of the patient monitor (see, for example, the illustration of an embodiment of the minimally invasive glucometer system 100 in FIG. 1, and/or FIG. 7B). Such an embodiment has the advantages of providing structural support to the strip reader dongle and clearly indicating to a user of the minimally invasive glucometer system 100 when the strip reader dongle is connected to the patient monitor. In another embodiment, the strip reader dongle may include a cable and/or cord that physically connects to the sensor connection of the patient monitor (see, for example, the illustration of a corded strip reader dongle connecting to an patient monitor in FIG. 7A).

[0068] Additionally, in block 306 the strip reader dongle may be authenticated and/or authorized by the patient monitor, as described above in reference to FIG. 2A. If the strip reader dongle is not authenticated and/or authorized, and/or the strip reader dongle is not compatible with the patient monitor, the user may be notified. For example, the user may be presented with the display of FIG. 7C. Alternatively, the authentication and/or authorization of the strip reader dongle may be accomplished in block 310 of FIG. 3.

[0069] In an embodiment, optional block 306 is not included in the configuration process. In this embodiment, the strip reader dongle is not

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physically connected to the patient monitor, but communication (in other words, data transmission) between the strip reader dongle and the patient monitor occurs wirelessly. Such wireless communications may be accomplished in any of the ways described above in reference to FIG. 2A and the optionally encrypted communications link 222. Alternatively, the strip reader dongle may be physically attached to the patient monitor, but communications may occur wirelessly.

[0070] Continuing to optional block 308, the patient monitor is changed into a glucometer. This may be accomplished, for example, by displaying the blood glucose measurement results on the display of the patient monitor (as described above with respect to the FIG. 2A). The patient monitor may automatically detect communications with, or the connection to, the strip reader dongle. In addition to detection methods discussed in the foregoing, the monitor may advantageously include an RFID reader that receives a signal when the dongle is within a proximity to the monitor and/or other detection methods an artisan would recognize after reviewing the disclosure herein.

[0071] Upon detecting the strip reader dongle, the patient monitor may, for example, update a user interface to include instructions and controls relevant to use of the patient monitor as a minimally invasive glucometer, begin communications with the strip reader dongle, authenticate the strip reader dongle, and/or begin quality control checks with the strip reader dongle, among other things. Alternatively, a user of the minimally invasive glucometer system may manually prompt the patient monitor to change to a glucometer.

[0072] In another embodiment, the patient monitor is not changed into a glucometer, but functions as a display in communication with an external glucometer. In this embodiment, the strip reader dongle may include additional processors and memory, among other things, for calculating blood glucose levels and displaying those levels. The data may then be transmitted to the patient monitor and displayed to the user.

[0073] In an embodiment, the patient monitor may be used for functions other than a glucometer while the strip reader dongle is attached to, or in communication with, the patient monitor. For example, the patient monitor may be used simultaneously, or at separate times, as a glucometer and a pulse oximeter, among other things. Thus, advantageously, according to various

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embodiments, the patient monitor provides additional functionality and patient monitoring abilities to the user.

[0074] At block 310 a glucometer minimally invasive protocol is applied. At this point, the patient monitor may function at least in part as a minimally invasive glucometer, interfacing and/or communicating with the strip reader dongle. For example, in this block the strip reader dongle may be authorized and/or authenticated, communication and/or transmission integrity checks may be performed, and/or the display of the patient monitor may display information relevant to performing a minimally invasive glucose test, among other things.

[0075] Then, in block 312, the minimally invasive glucometer system, now including the patient monitor and the strip reader dongle in communication with one another, interacts with the user and/or a caregiver. As described above, and as further described below, it is at this point that the user/caregiver may be directed by the minimally invasive glucometer system to, for example, insert a test strip into the strip reader dongle, apply blood to the test strip, and/or read the output of the glucometer measurement. Additionally, the user/caregiver may be instructed to perform a quality control test and/or linearity control test to ensure the results of the glucometer measurement are accurate.

[0076] In an embodiment, the strip reader dongle may alternatively be a prick reader dongle that operates by pricking the user's fingertip, or other area of the user's body, to obtain a blood sample to be analyzed.

[0077] In general, in some embodiments, the patient monitor or pulse oximeter of the minimally invasive glucometer system continue to function in their respective roles as a patient monitor or pulse oximeter, and not exclusively as glucometers. Thus, for example, the patient monitor 102 may continue reading blood oxygenation and pulse rate, while also functioning as a minimally invasive glucometer. In other embodiments, the patient monitor or pulse oximeter of the minimally invasive glucometer system may function exclusively, semi-exclusively, periodically, and/or only for a time, as a minimally invasive glucometer.

[0078] FIGS. 4A-4S illustrate exemplary user interfaces of the minimally invasive glucometer system 100 of FIG. 1, according to various embodiments of the present disclosure. In an embodiment, various of the example user interfaces of FIGS. 4A-4S may be displayed, for example, in

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response to the strip reader dongle being connected to, or brought into communication with, the patient monitor such that the patient monitor functions, at least in part, as a minimally invasive glucometer. As described above, the various user interfaces may be shown on a display of the minimally invasive glucometer system. The various user interface may be shown, for example, as a user of the minimally invasive glucometer system performs various functions and/or otherwise interacts with the system, as described in detail below. Further, as described above, the system may include one or more buttons, and/or the display of the system may be a touch-sensitive display such that a user may interact with, and/or select, various aspects of the system direct via the touch-sensitive display.

[0079] FIGS. 4A-4D illustrate exemplary settings user interfaces of the system. For example, in the various user interfaces a user of the minimally invasive glucometer system may select to perform a glucose test, read test results, adjust various settings, perform a quality control of the system, transfer test results (for example, to another device or computer system), set and/or view patient-related information, and/or view help information. In an embodiment the user may select the operating and/or test mode of the minimally invasive glucometer system 100. In an embodiment, the minimally invasive glucometer system 100 may be set to a maximum sensitivity mode, a normal sensitivity mode, or a multi mode. The operating mode may be selected by the user before the measurement process begins. The user may be prompted with instructions for the selected mode. For example, in normal sensitivity mode, a true parameter value is estimated by providing a predicted parameter value based on a measured set of input values. This mode can be useful where a quick estimate of a predicted parameter value is needed. In maximum sensitivity mode (max mode), more accurate results may be obtained. In multi mode, successive measurements may be taken. For example, three separate input values may be measured, and the sensor may be reapplied between measurements. A predicted parameter value may be calculated for each of the measured input values. Optionally, one or more of the predicted parameter values may be dropped and the remaining values may be averaged to yield a final prediction. For example, of three predicted parameter values, the median value may be averaged with the next closest value and provided to the user. The multi-mode

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may provide a more accurate measurement with a higher confidence than the normal mode and/or the max mode. Additional examples of systems and processes of multiple parameter measurements may be found in at least U.S. Patent Application No. 13/548637, filed July 13, 2012, and entitled "MULTIPLE MEASUREMENT MODE IN A PHYSIOLOGICAL SENSOR" (now published as U.S. Patent Application Publication No. 2013/0041591), which application is hereby incorporated by reference herein in its entirety and for all purposes.

[0080] In an embodiment, the user may interact with the user interface to take various actions with respect to results of minimally invasive glucose tests that have been performed. For example, the user may email test results, to for example, their physician. The user may also optionally print the test results, and/or export the test results to, for example, an external memory such as a MicroSD card. The user may also delete the test results.

[0081] In various embodiments the system may include various patient information interfaces. For example, via a user interface the user may input their user id, patient id, birthday, and gender. In another example, via the user interface of FIG. 4D, the user (for example, a patient) may set and/or view various patient information and/or patient/user preferences. For example, the user/patient may set a height and weight, may add notes, and/or may designate a test digit (for example, a particular finger or fingers from which blood will be taken for the minimally invasive glucose test). The minimally invasive glucometer system 100 may thus, for example, record and/or track from which finger the blood is obtained on each blood glucose reading, and/or may instruct the user on which finger to use.

[0082] FIGS. 4D-4E illustrate exemplary reader dongle connection interfaces. For example, in an embodiment, in FIG. 4D, the user is instructed to attach the reader dongle 104 to the patient monitor 102. In this embodiment, the reader dongle 104 includes a cord that attaches to the patient monitor 102, in this example, a Masimo Pronto-7 spot check monitor. In another embodiment, in FIG. 4E, the reader dongle 104 is a self-contained unit that plugs into the patient monitor 102. In an embodiment the system may include an interface notifying the user when an incompatible reader dongle 104 has been attached to the patient monitor 102. Such an interface may be presented to the user when, for example,

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the front-end interface 230 of FIG. 2A indicates that the reader dongle 104 does not have the correct optional encryption PCB 220, the reader dongle 104 is incompatible with the patient monitor 102, the reader dongle 104 cannot be authenticated, and/or the reader dongle 104 is not authorized to interface with the patient monitor 102.

[0083] The system may further include, in various embodiments, various quality control and/or quality control test user interfaces. For example, FIGS. 4G-4K illustrate various example quality control test user interfaces. In an embodiment, the minimally invasive glucometer system 100 runs quality control cycles periodically to ensure that proper measurements are being obtained from the strip reader PCB 210. In an embodiment, the system may instruct the user to run a quality control cycle when needed and/or according to a schedule (for example, as shown in FIG. 4G). Further, as shown in FIG. 4H, the user may manually initiate quality control and/or linearity control cycles, may set a frequency with which quality control cycles run, and/or may view quality control and/or linearity control cycle results. When a quality control cycle is run, the user may be instructed by the minimally invasive glucometer system 100 to insert a test strip, apply a control solution (for example, as shown in FIG. 4I), and/or run a test. In an embodiment, the user may view various details related to the quality control of the system, for example as shown in the user interface of FIG. 4J. Additionally, as shown in the example user interface of FIG. 4K, the user may be given an indication of a pass or a fail of a quality control test. As shown, a quality control test/cycle may include testing multiple control solutions with particular strip lots. In an embodiment, passing all quality control and/or linearity tests may be required before a glucose test may be run. In an embodiment, three tests are run for each quality control cycle. For example, often strip reader manufacturers provide solutions for testing strip readers. The user drips solution onto a test strip and inserts the strip into the reader. The solution is designed to cause the reader, when functioning properly, to provide a measurement within a provided range of acceptable measurements. These solutions may include three bottles corresponding to low, regular or medium and high solutions, designed to cause the reader to provide measurement in the low, medium and high ranges. The interface may guide the user through, for example, using these solutions to verify accurate operation of the strip reader.

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[0084] The system may further include, in various embodiments, various linearity control test user interfaces. In an embodiment, linearity tests are run periodically and automated. In an embodiment, five tests are run for each linearity control cycle.

[0085] Advantageously, in various embodiments, automated quality control and linearity tests help ensure that the minimally invasive glucometer system 100 is calibrated and produces an accurate and precise result when measuring glucose levels in a user's blood across test strip lots and for various environmental conditions. In an embodiment, the information displayed may include time and date of last calibrations and next calibrations, may include information on how many calibrations have been accomplished and/or how many remain. For example, a timeline may advantageously indicate where in a calibration process the current measurements fall. Moreover, the timeline may include days, months, and years tabs to quickly organize information regarding device usage.

[0086] FIGS. 4L-4R illustrate exemplary glucose testing interfaces. For example, in FIGS. 4L-4M, the user is instructed to insert a test strip (such as the disposable glucose strip 110), and apply blood to the strip. In FIG. 4N the user is instructed to remove a test strip to proceed with a new test. In FIG. 4O the user is notified that the system is ready for a test to be run, for example, after a test strip has been inserted into the system. For example, the user may press the "Test" button of the user interface of FIG. 4O to begin a test on an inserted test strip. In FIG. 4P, a test is run and example test results are shown. In FIG. 4Q, various test results are shown in a table. For example, the user may store and/or view various test results taken at different times in a table, as shown. In an embodiment, the user may email test results to, for example, their physician. In FIG. 4R, an example user interface is shown in which the system indicates to the user that the test is incomplete as a test strip has been determined to be defective.

[0087] FIGS. 4S-4T illustrate exemplary informational user interfaces, such as instructions concerning the use of the minimally invasive glucometer system 100 and/or information about glucose measurements. Additionally, as shown in FIGS. 4S-4T, the system may display glucose measurements in various units (for example, mg/dL and/or mmol/L).

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[0088] Advantageously, according to various embodiments the minimally invasive glucometer system enables minimally invasive blood glucose monitoring using a patient monitor. In other words, the same device that is used by the user for blood oxygen saturation monitoring (among other things) may also be used for blood glucose monitoring. The minimally invasive glucometer system may thus reduce the number of devices that a user must have to measure blood glucose levels and the various other levels that may be measured by a patient monitor (such as blood oxygen saturation ("SpO2"), pulse rate ("PR"), pethysmographic information, total hemoglobin (SpHb™), oxygen content (SpCO™), methemoglobin (SpMet®), carboxyhemoglobin (SpCO®) and PVI®).

[0089] Although the foregoing minimally invasive glucometer system has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, alternate protocols may be implemented or the like. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present disclosure is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

[0090] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

[0091] The various illustrative logical blocks, modules, routines, and algorithm steps described in connection with the embodiments disclosed herein may be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. The described functionality may be implemented in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the disclosure.

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[0092] The steps of a method, process, routine, or algorithm described in connection with the embodiments disclosed herein may be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software module may reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, or any other form of a non-transitory computer-readable storage medium. An example storage medium may be coupled to the processor such that the processor may read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor. The processor and the storage medium may reside in an ASIC.

[0093] Conditional language used herein, such as, among others, “can,” “could,” “might,” “may,” “for example,” and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular embodiment. The terms “comprising,” “including,” “having,” and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term “or” is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term “or” means one, some, or all of the elements in the list.

[0094] Conjunctive language such as the phrase “at least one of X, Y and Z,” unless specifically stated otherwise, is to be understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z, or a combination thereof. Thus, such conjunctive language is not generally intended to imply that certain embodiments require at least one of X, at least one of Y, and at least one of Z to each be present.

[0095] Moreover, terms used herein are intended to have their broad ordinary meaning understood within the art. The term “and/or” is intended to

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mean that one, any combination of two or more, or all combinations of the corresponding listed elements are appropriate; however, it is not intended to mean that all combinations must be accomplished.

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WHAT IS CLAIMED IS:

1. A spot check monitoring system using a monitor configured to accept signals responsive to light attenuated by body tissue comprising:
a minimally invasive glucose reader; and
a patient monitor in communication with said minimally invasive glucose reader,
wherein, when a glucose level is read by said minimally invasive glucose reader, said glucose level is transmitted to said patient monitor,
wherein said patient monitor is configurable as an oximeter and is configurable to display said glucose level when said glucose level is transmitted to said patient monitor.
2. The spot check monitoring system of Claim 1, further comprising a dongle, wherein said dongle houses said minimally invasive glucose reader.
3. The spot check monitoring system of Claim 1, further comprising a reader board, wherein said minimally invasive glucose reader is mounted on said reader board.
4. The spot check monitoring system of Claim 3, further comprising an encryption controller configured to encrypt information from said minimally invasive glucose reader.
5. The spot check monitoring system of Claim 4, further comprising an encryption board, wherein said encryption controller is mounted on said encryption board.
6. The spot check monitoring system of Claim 5, wherein said encryption board and said reader board are different boards.
7. The spot check monitoring system of Claim 1, further comprising strips configured to be read by said minimally invasive glucose reader, wherein said strips comprise source identifying strips.

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8. The spot check monitoring system of Claim 1, wherein when said patient monitor is configured as said oximeter, said patient monitor communicates with an optical sensor that outputs signals responsive to light attenuated by patient tissue carrying pulsing blood, said patient monitor receiving said signals and configured to process said signals to determine physiological parameters including at least an indication of oxygen saturation of the patient tissue.

9. A method of converting a patient monitor to a spot check glucometer, comprising:

- providing a minimally invasive glucose reader configured to accept strips carrying samples to be analyzed;

- providing a patient monitor configured to communicate with an optical sensor to receive signals responsive to light attenuated by tissue of a patient carrying pulsing blood, to process said signals, to determine one or more measurements of physiological parameters of said patient including at least oxygen saturation;

- associating said reader with said patient monitor causing said patient monitor to change to a spot check glucometer;

- inserting one of said strips into said reader; and

- displaying on a display of said patient monitor measurement data responsive to said sample on said inserted strip.

10. The method of Claim 9, wherein said associating comprises establishing electrical communication between said reader and said patient monitor.

11. The method of Claim 10, wherein said establishing electrical communication comprises attaching a dongle housing said reader.

12. The method of Claim 10, wherein said establishing electrical communication comprises establishing encrypted communication with said monitor.

13. The method of Claim 12, wherein establishing electrical communication comprises establishing communication through an encryption board.

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14. An encrypted source-identifying glucose strip reader configured to change an oximeter into a glucometer, said reader comprising:

a strip reader configured to accept samples on a strip and output a signal responsive to characteristics of said sample, said characteristics including a measure of glucose in said sample;

a controller communicating with said strip reader to determine said measure of glucose from said sample and output data indicative of at least said measure; and

an encryption controller configured to receive said data from said controller and output encrypted data to an oximeter configured to modify its operation to present display indicia to a user of the oximeter, the display indicia responsive to said measure of said glucose in said sample, the encrypted data identifying by its encryption the source of the reader.

15. The reader of Claim 14, further comprising a reader board, wherein said strip reader and said controller are mounted on said reader board.

16. The reader of Claim 14, further comprising an encryption board, wherein said encryption controller is mounted on said encryption board.

17. The reader of Claim 16, wherein said strip reader and said controller are mounted on said encryption board.

18. The reader of Claim 14, further comprising a dongle, wherein the strip reader, the controller and the encryption controller are housed within a dongle.

19. The reader of Claim 18, wherein said dongle comprises a connector, said connector having a mechanical and pin layout that mechanically mates with an oximeter connector normally connected to a noninvasive optical sensor.

20. The reader of Claim 18, wherein said strip reader and said controller comprises an OEM strip reader and controller.

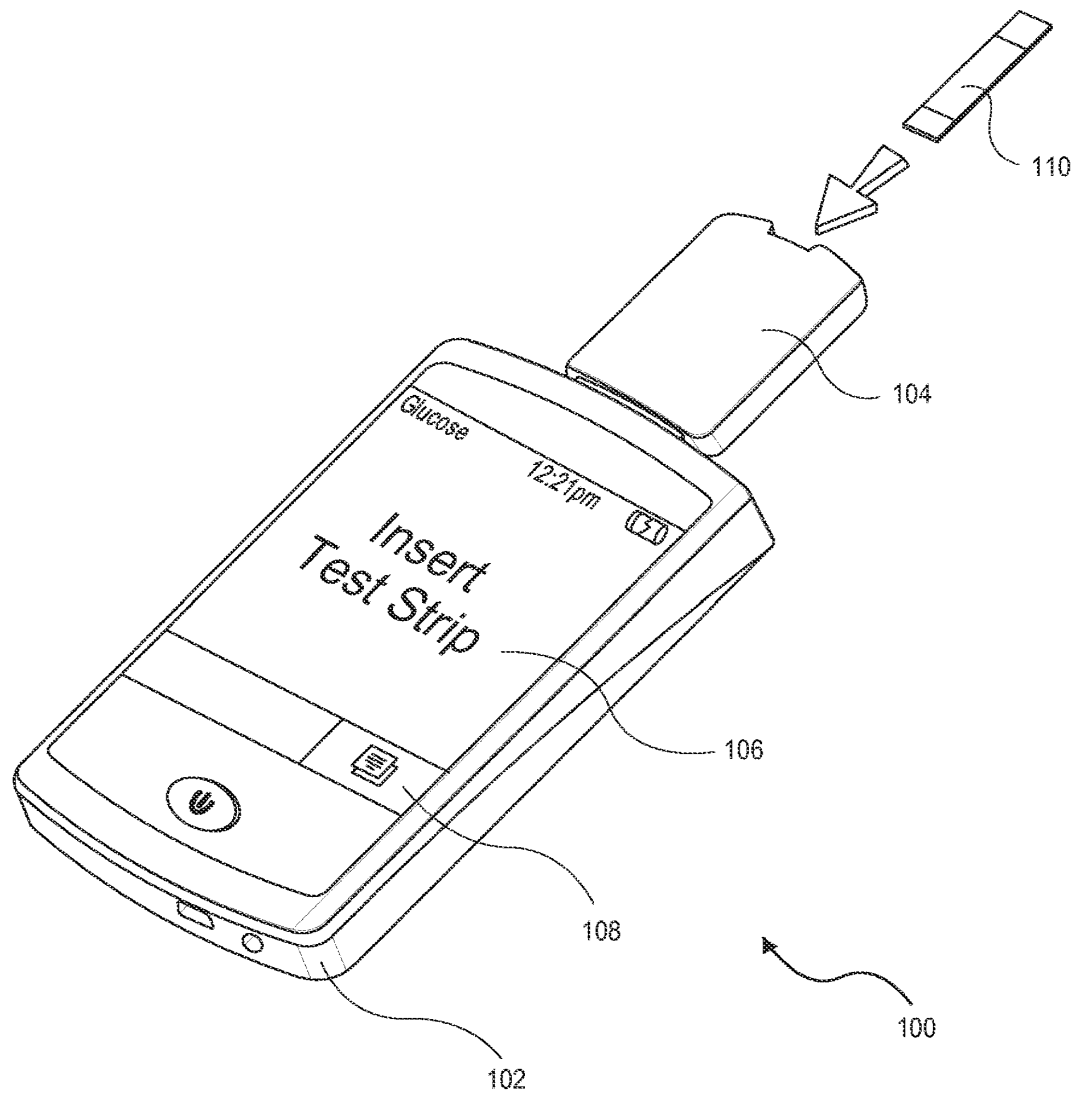


FIG. 1

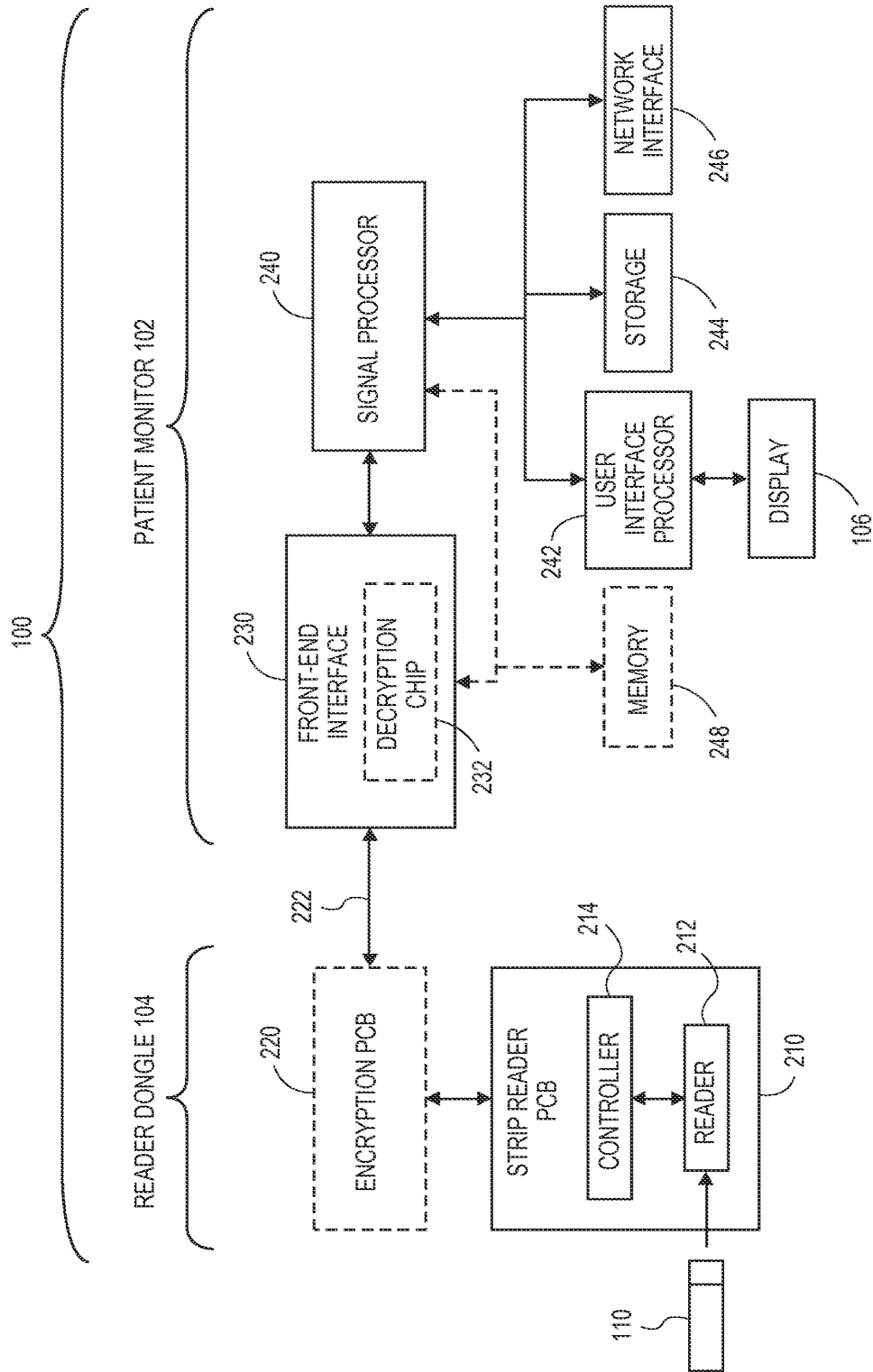
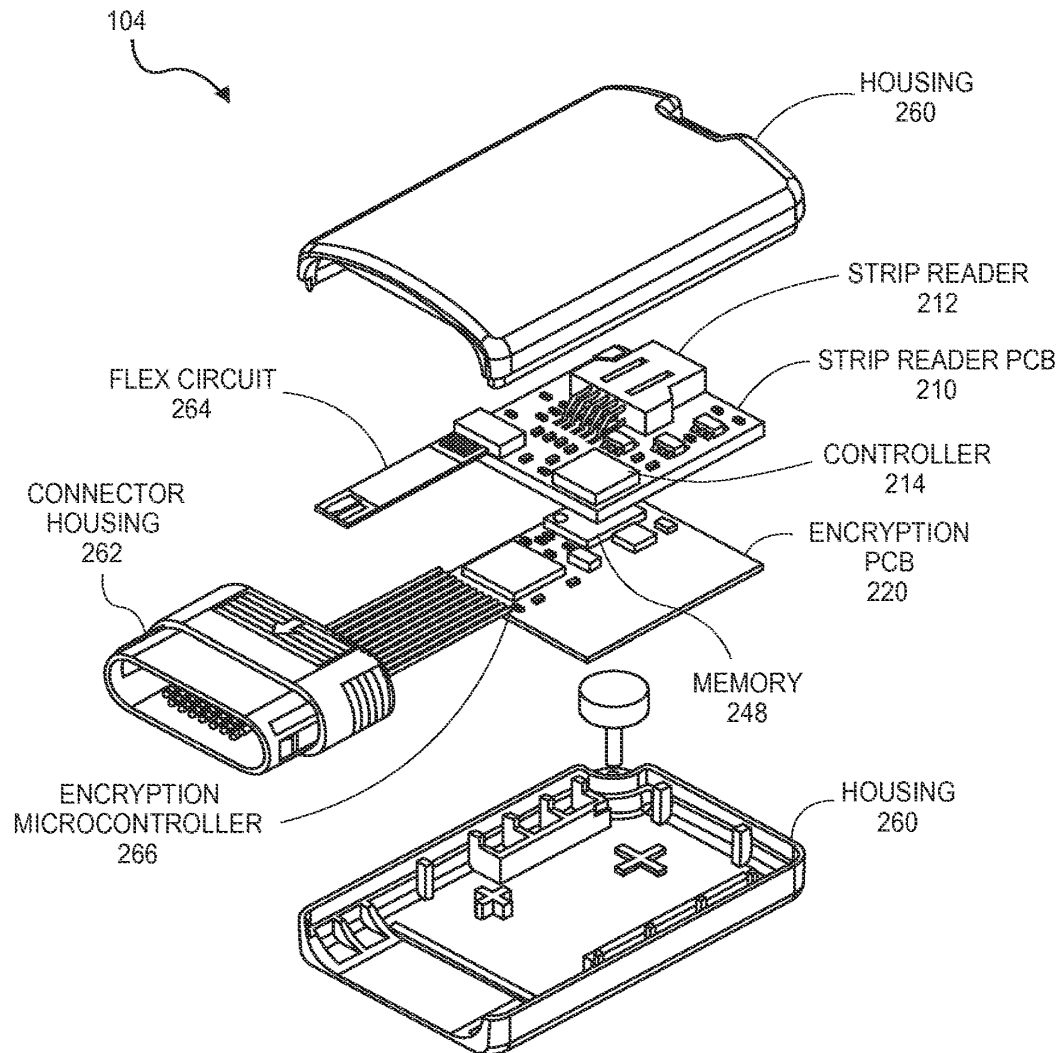


FIG. 2A

**FIG. 2B**

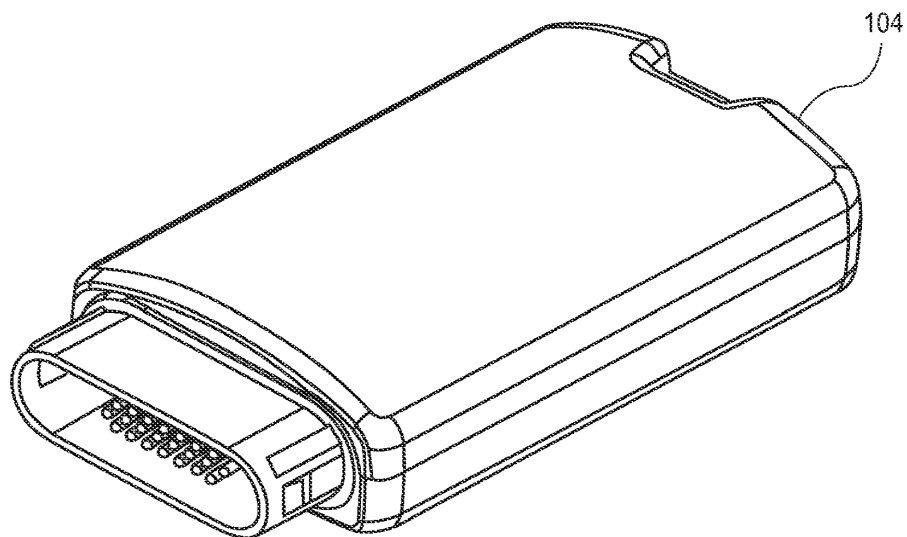


FIG. 2C

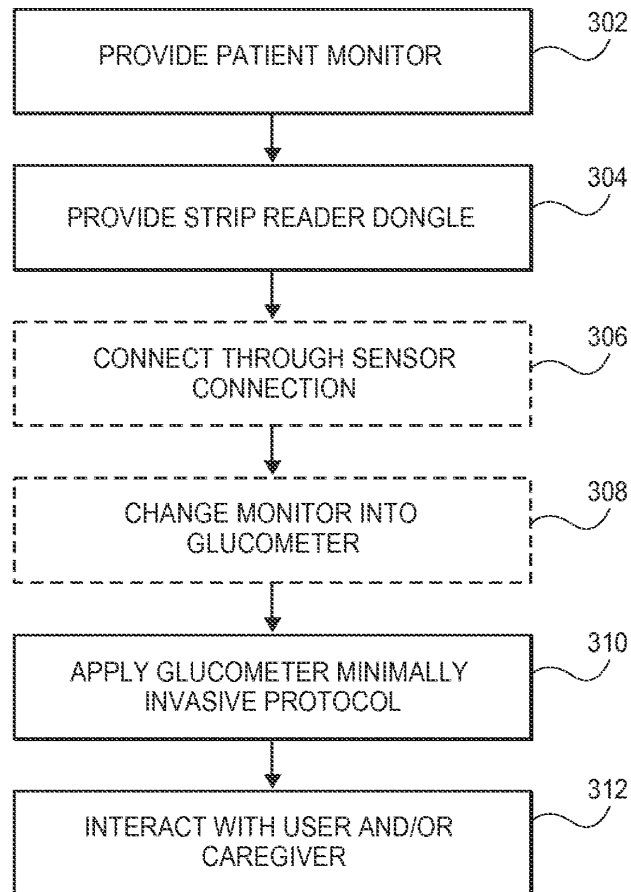


FIG. 3

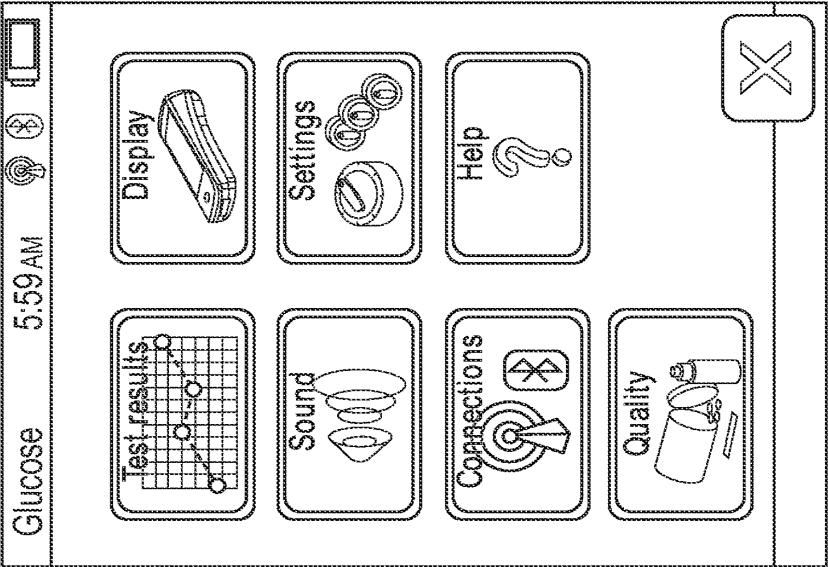


FIG. 4A

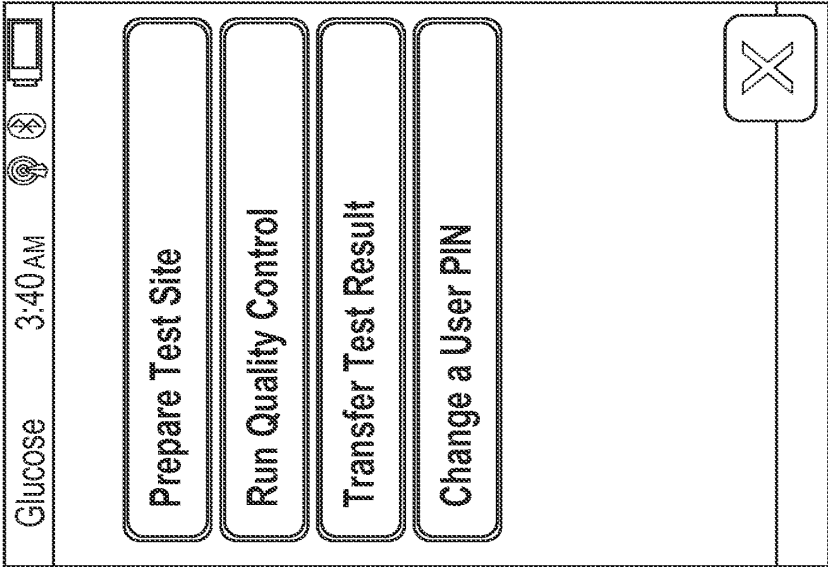


FIG. 4B

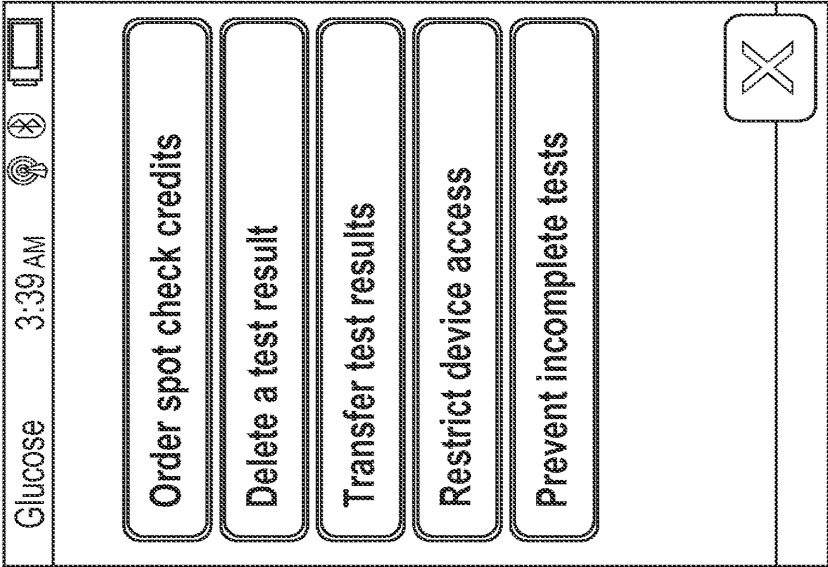


FIG. 4C

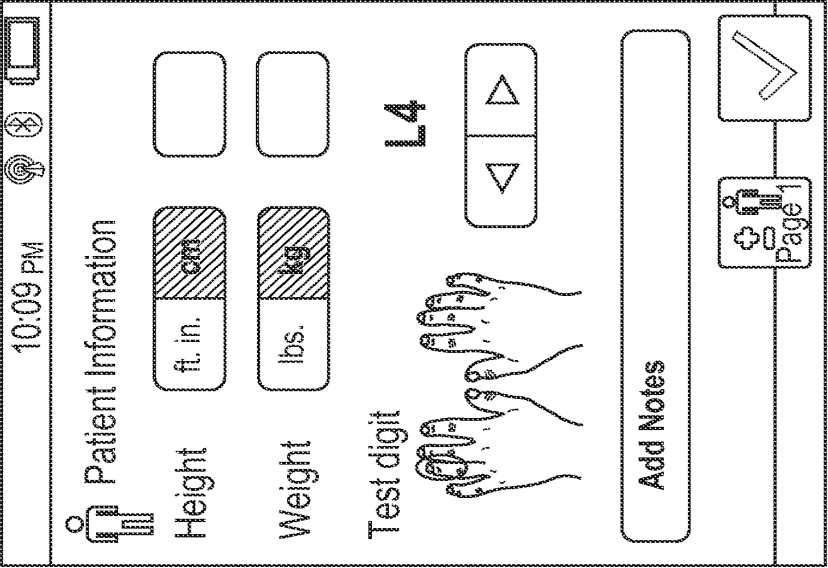


FIG. 4D

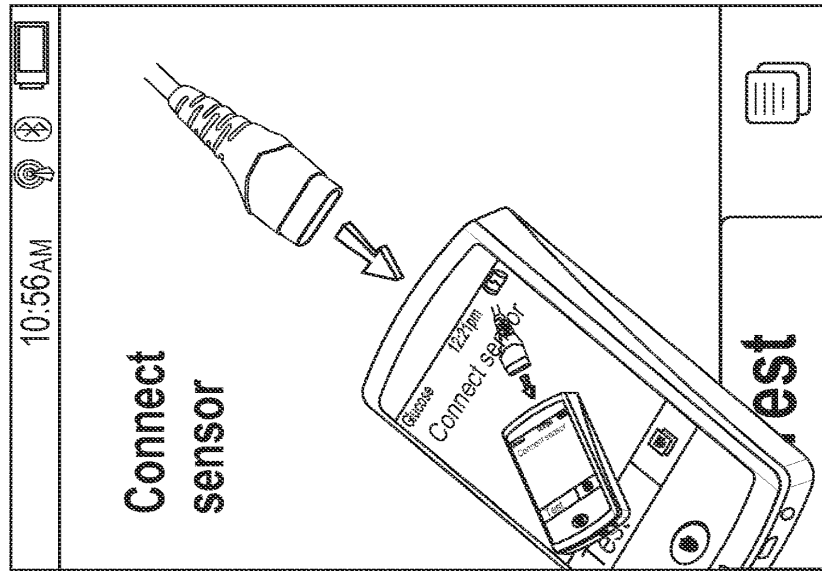


FIG. 4E

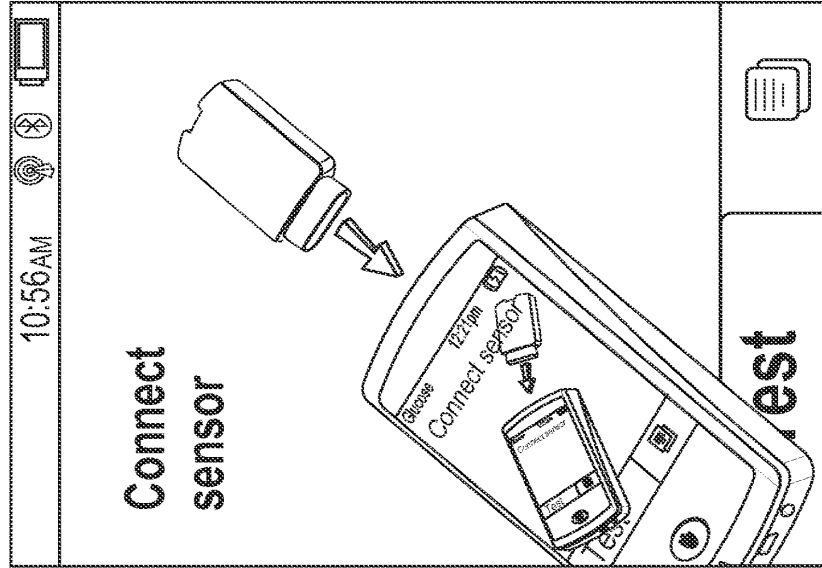


FIG. 4F

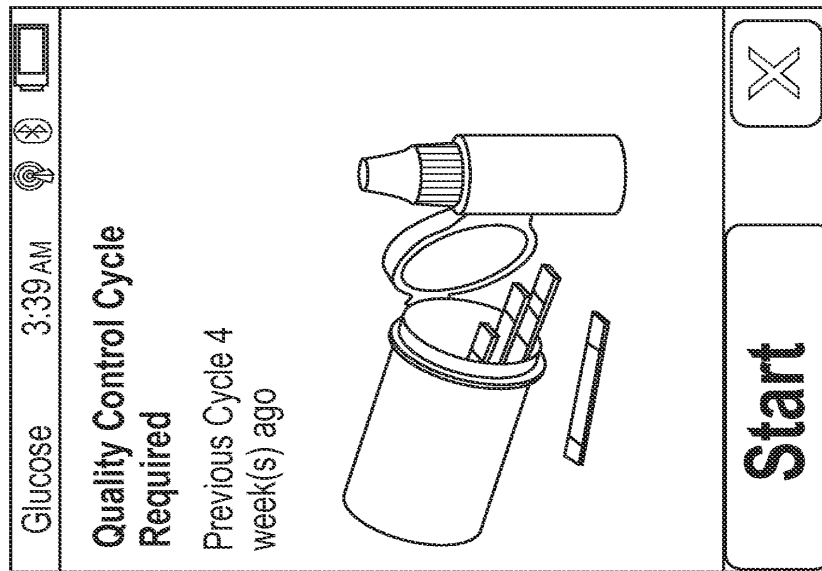


FIG. 4G

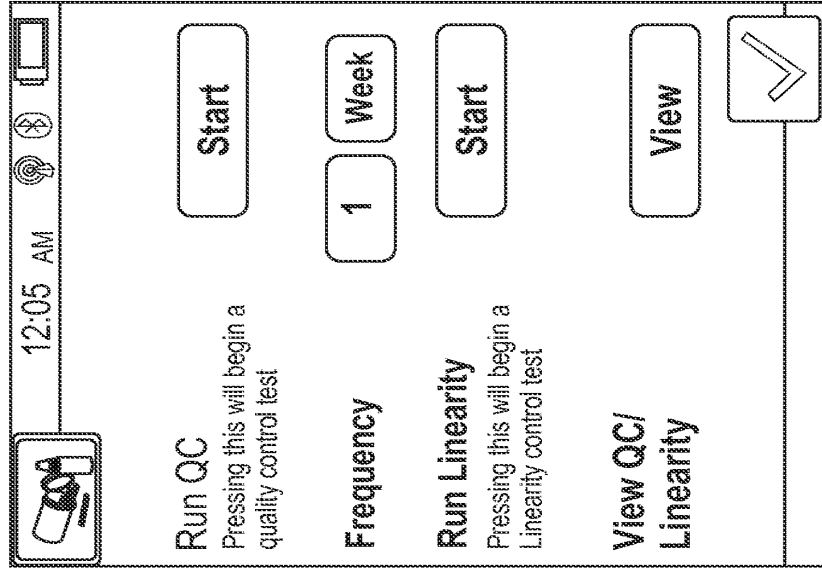


FIG. 4H

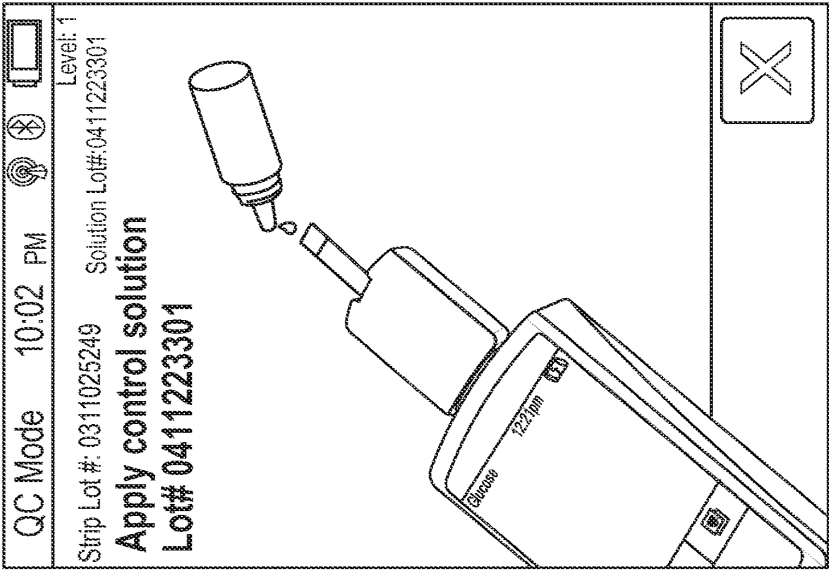


FIG. 4I

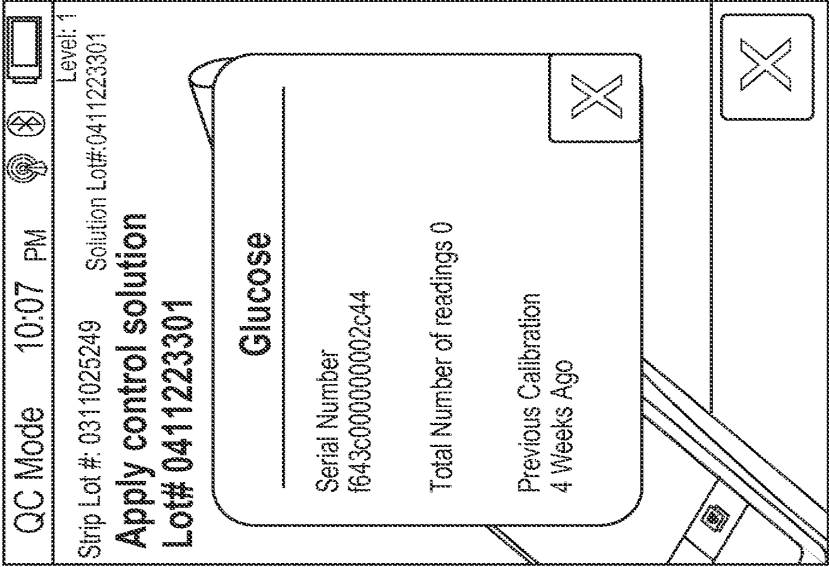


FIG. 4J

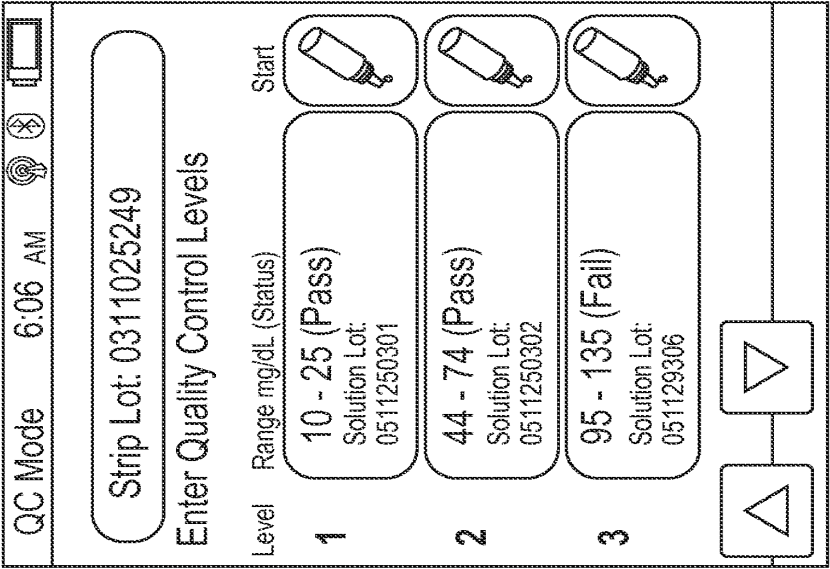


FIG. 4K

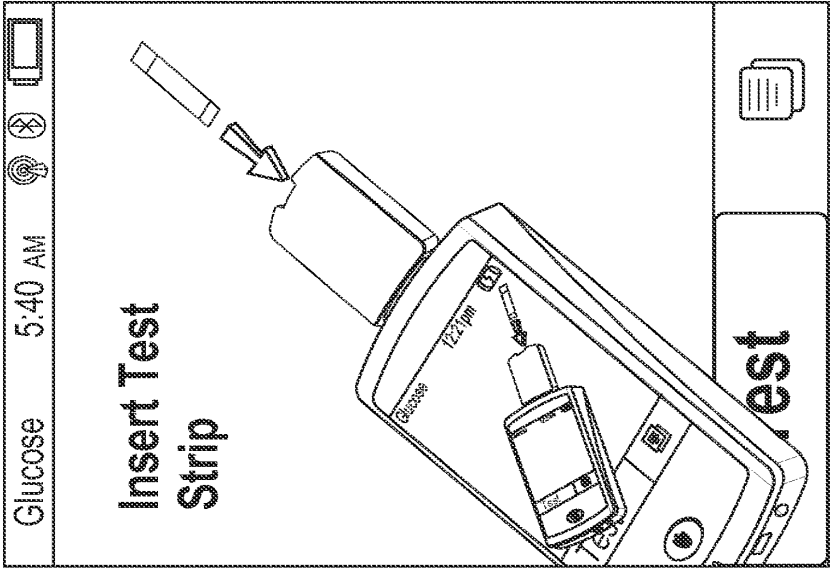


FIG. 4L

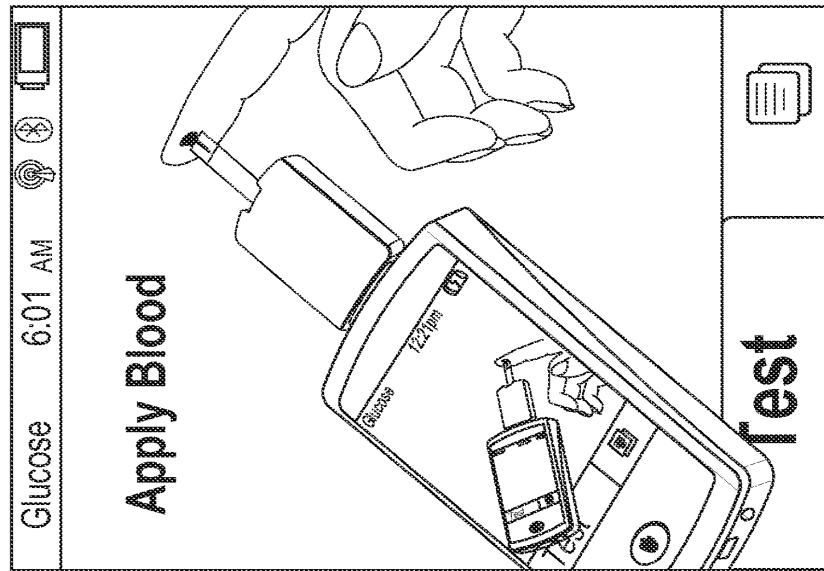


FIG. 4M

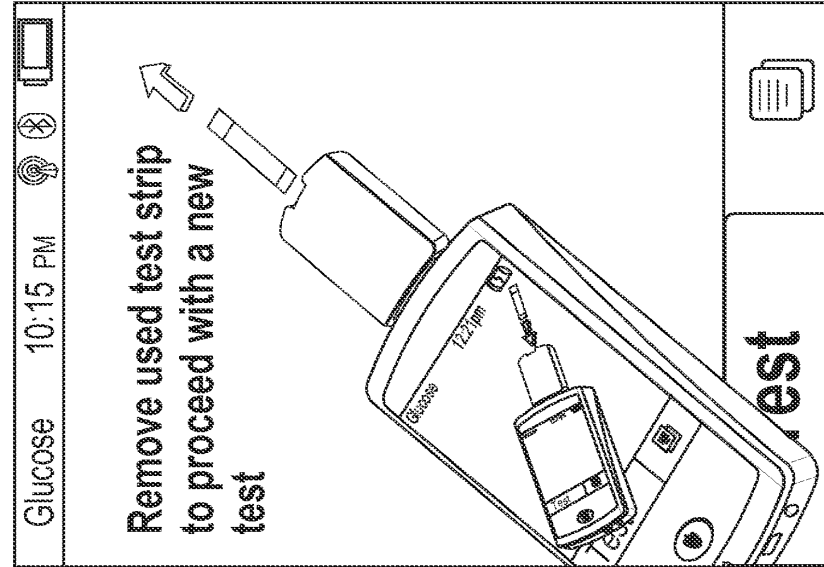


FIG. 4N

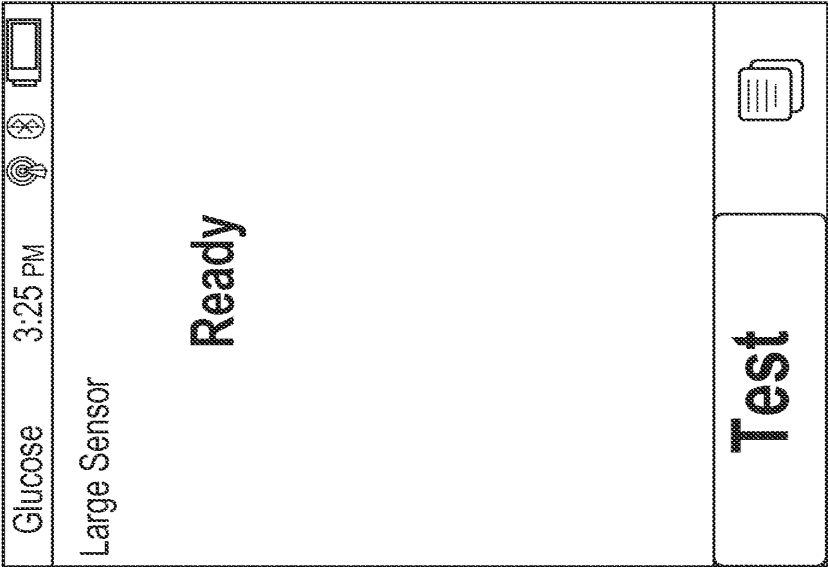


FIG. 40

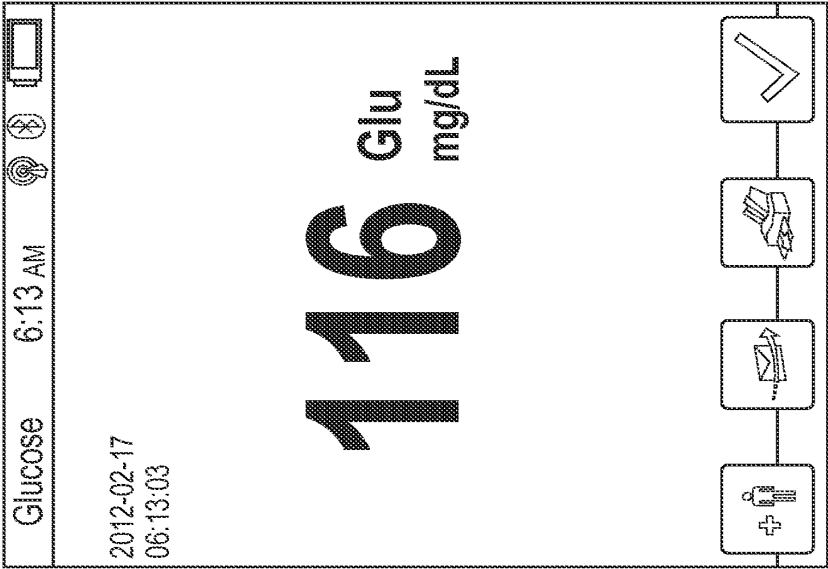


FIG. 4P

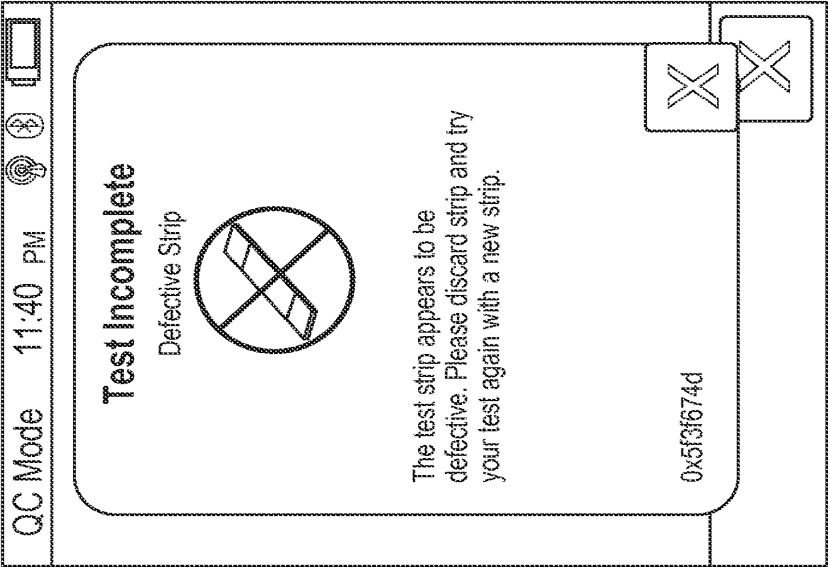


FIG. 4R

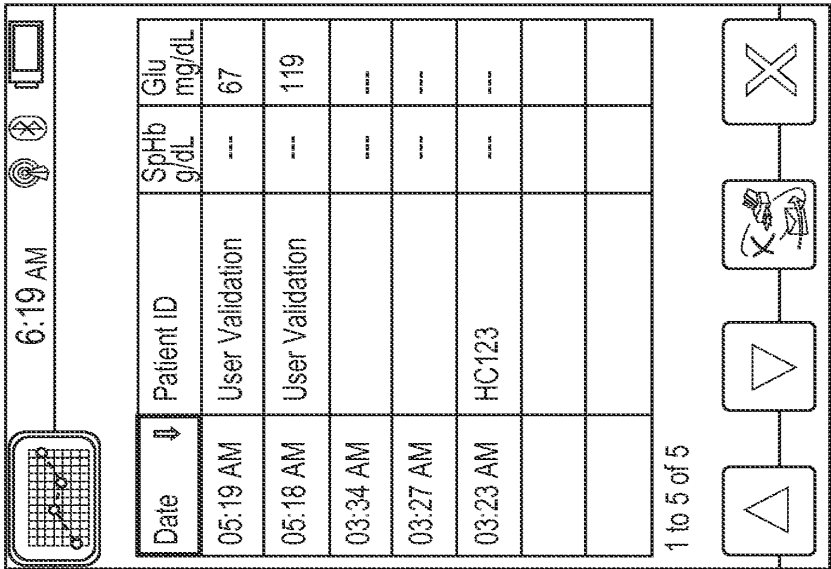


FIG. 4Q

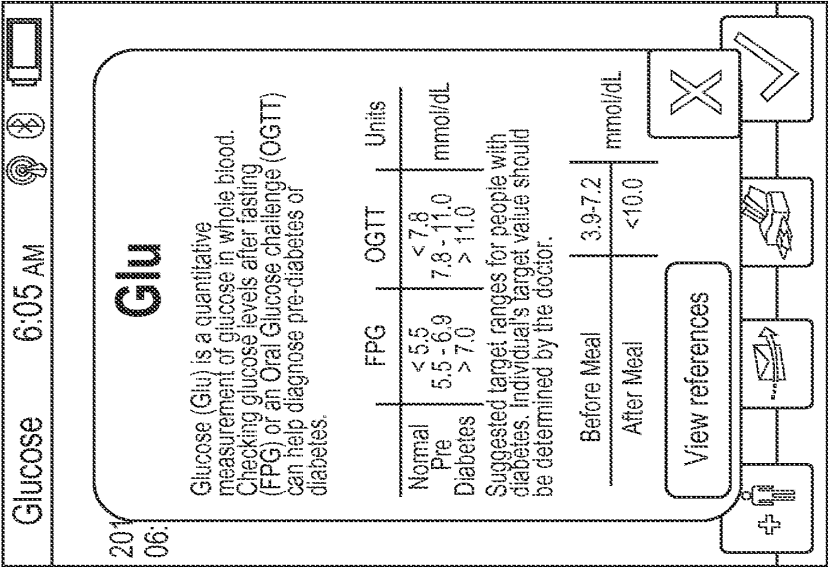


FIG. 4T

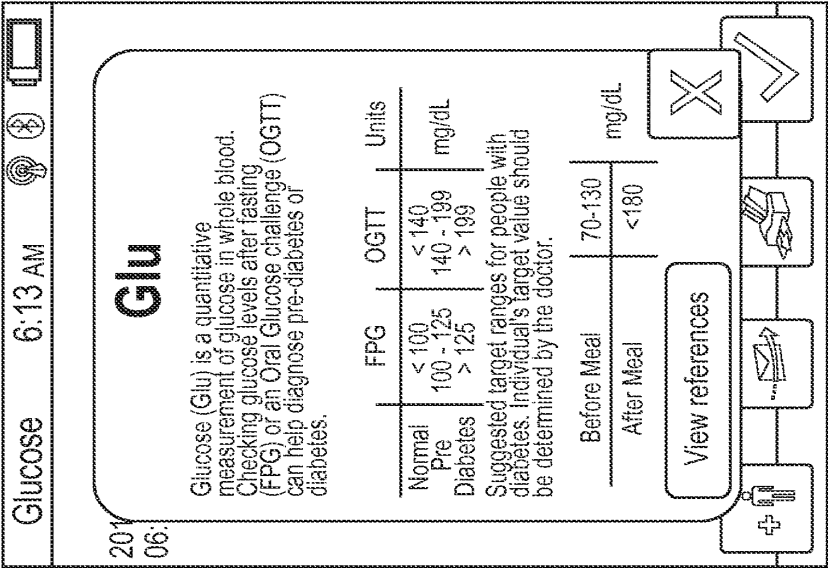


FIG. 4S

CX-1622

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/020359

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/145 A61B5/1455
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, COMPENDEX, EMBASE, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 2012/075322 A2 (MASIMO LABORATORIES INC [US]; LAMEGO MARCELO M [US]; KIANI MASSI JOE E) 7 June 2012 (2012-06-07)	1-6,8-13
Y	abstract paragraphs [0009] - [0016], [0055] - [0057], [0097] - [0100]; figures 1-5 -----	14-20
X	US 2011/213218 A1 (WEINER BERT A [US] ET AL) 1 September 2011 (2011-09-01)	1-3,7-11
Y	abstract	14-20
A	paragraphs [0010] - [0013], [0019], [0034], [0036], [0043]; figure 1 -----	4-6
X	WO 01/28416 A1 (HEALTHETECH INC [US]) 26 April 2001 (2001-04-26)	1-3,8-11
A	----- -/--	4-7, 12-20

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 June 2014

Date of mailing of the international search report

04/07/2014

Name and mailing address of the ISA/

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Fax: (+31-70) 340-3016

Authorized officer

Juárez Colera, M

Form PCT/ISA/210 (second sheet) (April 2005)

CX-1622

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/020359

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	abstract paragraphs [0013], [0014], [0059] - [0061]; claim 1; figure 8 -----	4-7, 12-20
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CX-1622

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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Form PCT/ISA/210 (patent family annex) (April 2005)

Docket No.: CERCA.002C1

Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

Inventors	:	Jeroen Poeze et al.
App. No.	:	12/829,352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Chu Chuan Liu
Art Unit	:	3777
Conf. No.	:	8366

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a First Office Action, but before the mailing date of a Final Action and before the mailing date of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 CFR 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Application No.: 12/829,352
Filing Date: July 1, 2010

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 19, 2015

By: /Scott Cromar/ _____
Scott A. Cromar
Registration No. 65,066
Attorney of Record
Customer No. 20995
(949) 760-0404

19773985

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829,352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze et al.
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Chu Chuan Liu
SHEET 1 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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	3	5,122,925	06/16/1992	Inpyn	
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	27	8,428,674	04/23/2013	Duffy et al.	
	28	8,602,971	12/10/2013	Farr	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829,352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze et al.
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Chu Chuan Liu
SHEET 2 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29	8,688,183 (CERCA.008A)	04/01/2014	Bruinsma et al.	
	30	8,909,310 (CERCA.003D1)	12/09/2014	Lamego et al.	
	31	2010/0030040	02/04/2010	Poeze et al.	
	32	2013/0317370 (CERCA.007C1)	11/28/2013	Dalvi et al.	
	33	2014/0066783 (CERCA.006C1)	03/06/2014	Kiani et al.	
	34	2014/0296664 (CERCA.008C1)	03/27/2014	Bruinsma et al.	
	35	2014/0155712 (CERCA.003D1)	06/05/2014	Lamego et al.	
	36	D692,145	10/22/2013	Al-Ali et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	37	WO 2014/149781 (CERCA.082WO)	09/25/2014	Cercacor Laboratories, Inc.		
	38	WO 2014/158820 (CERCA.067WO)	10/02/2014	Cercacor Laboratories, Inc.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	39	Japanese Office Action, re JP Application No. 2011-516895, mailed September 2, 2014, with translation. (CERCA.007JP).	√
	40	European Office Action issued in application no. 10763901.5 on 08/27/2014. (CERCA.008EP).	
	41	KANUKURTHY et al., "Data Acquisition Unit for an Implantable Multi-Channel Optical Glucose Sensor", Electro/Information Technology Conference, Chicago, IL, USA, May 17-20, 2007, pp. 1-6	
	42	SMITH, "The Pursuit of Noninvasive Glucose: 'Hunting the Deceitful Turkey'", 2006	
	43	SMALL et al., "Data Handling Issues for Near-Infrared Glucose Measurements", http://www.ieee.org/organizations/pubs/newsletters/leos/apr98/datahandling.htm , accessed 11/27/2007	

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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language Translation is attached.

SUPPLEMENTAL APPLICATION DATA SHEET**Application Information**

Application Number:: 12/829352
Filing Date:: July 1, 2010
Application Type:: Regular
Subject Matter:: Utility
Title:: MULTI-STREAM DATA COLLECTION SYSTEM FOR
NONINVASIVE MEASUREMENT OF BLOOD
CONSTITUENTS
Attorney Docket Number:: CERCA.002C1

Applicant 1 Information

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Supplemental 12/829352 July 1, 2010 1/19/15

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Supplemental 12/829352 July 1, 2010 1/19/15

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Applicant 8 Information

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Representative Information

Representative Customer Number:: 20995

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	Continuation of	12/534827	2009-08-03
12/534827	non provisional of	61/086108 <u>61/086060</u>	2008-08-04
12/534827	non provisional of	61/086108	2008-08-04
12/534827	non provisional of	61/086063	2008-08-04
12/534827	non provisional of	61/086057	2008-08-04
12/534827	non provisional of	61/091732	2008-08-25

Docket Number: CERCA.002C1

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	Continuation of <u>Continuation in part of</u>	12/497528	2009-07-02
12/497528	non provisional of	61/086060	2008-08-04
12/497528	non provisional of	61/086108	2008-08-04
12/497528	non provisional of	61/086063	2008-08-04
12/497528	non provisional of	61/086057	2008-08-04
12/497528	non provisional of	61/078228	2008-07-03
12/497528	non provisional of	61/078207	2008-07-03
12/497528	non provisional of	61/091732	2008-08-25
12/497528	Continuation in part of	29/323409	2008-08-25
12/497528	Continuation in part of	29/323408	2009-12-22
This Application	Continuation of <u>Continuation in part of</u>	12/497523	2009-07-02
12/497523	non provisional of	61/086060	2008-08-04
12/497523	non provisional of	61/086108	2008-08-04
12/497523	non provisional of	61/086063	2008-08-04
12/497523	non provisional of	61/086057	2008-08-04
12/497523	non provisional of	61/078228	2008-07-03
12/497523	non provisional of	61/078207	2008-07-03
12/497523	non provisional of	61/091732	2008-08-25

Foreign Priority Information

Country::	Application Number::	Filing Date::	Priority Claimed::
			No

Assignment Information

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Dated: January 19, 2015

By: /Scott Cromar/ _____
Scott A. Cromar
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Attorney of Record
Customer No. 20995
(949) 760-0404

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CX-1622

PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		<input type="checkbox"/> To be Mailed	
Substitute for Form PTO-875				12/829,352		07/01/2010			
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input checked="" type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A		330			
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		330			
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	01/19/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		0	
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.									
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".									
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	09/17/2014
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FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
09/17/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Office Action Summary	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 06/27/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-22 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-22 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 06/27/2014.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.

4) ☐ Other: ____.

Application/Control Number: 12/829,352
Art Unit: 3777

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DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/04/2014 has been entered.
3. Claims 1-22 are pending for examination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (USPN 5,362,966 - cited in previous action) in view of Schulz et al. (USPN. 7,254,434 – applicant cited) and further in view of Sakai et al. (USPN 5,131,391 – applicant cited). In regard to claim 1, Rosenthal discloses a noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a

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measurement site on a patient (Col 1 line 1 - Col 2 line 41 and Fig. 1), the sensor comprising: an optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15) configured to emit optical radiation onto said tissue at said measurement site (Fig. 1); at least one photodetector (element 8, Fig. 1) configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (Fig. 1) and output at least one respective signal stream responsive to said detected optical radiation (through connection between element 8 and processor 10, Fig. 1); a housing positioning said optical source and said at least one photodetector with respect to said measurement site (element 28 in element 1, Fig. 1); a thermistor (element 29, Fig. 1) operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 and Col 2 lines 25-41). Rosenthal does not specifically said housing forming a clip sensor and including: a first shell housing said optical source; a second shell hinged to the first shell and housing said photodetector; a spring disposed between and urging together the shells; and a heat sink operably connected to the first shell of said housing. Schulz teaches a housing forming a clip sensor (Figs. 1-6) and including: a first shell (element 210, Fig. 2; element 410, Fig. 4; element 610, Fig. 6) housing an optical source (element 250, Fig. 2; associated elements in Fig. 4); a second shell (element 240, Fig. 2; element 420, Fig. 4; element 620, Fig. 6) hinged to the first shell (Figs. 1-6) and housing said photodetector (element 260, Fig. 2); a spring disposed between and urging together the shells (element 294, Fig. 2; elements 310, Fig. 3; element 430, Fig. 4; element 630, Fig. 6). It is known that a separate sensor structure is considered as much

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easier for performing regular maintenances such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a separate clip sensor (Schulz) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts. Rosenthal as modified by Schulz does not specifically disclose a heat sink integrated as a single piece with the first shell of said housing. Sakai teaches a heat sink integrated as a single piece with a sensor (element 72, Fig. 5 and associated descriptions) for radiating heat toward the outside of the sensor (Fig. 5). The light source utilized in the clip sensor structure taught by Rosenthal as modified by Schulz (Figs. 1-6 of Schulz) is enclosed by the upper shell structures. It is known that a heat sink(s) can be utilized to dispensing heat generated by light emitting sources and maintain the light sources at a moderate operating temperature as evidenced by Aronow (USPN 5,851,178 - cited in previous action). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Schulz) to incorporate the use of a heat sink integrated as a single piece (Sakai) with the first shell structure which encloses the light source(s) in order to more efficiently dispensing heat toward outside of the sensor housing and obtain more stable operation performance of the light source(s).

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In regard to claim 2, Rosenthal as modified by Schulz and Sakai discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and finger, Figs. 1-6 of Schulz).

In regard to claim 3, Rosenthal as modified by Schulz and Sakai discloses at least a portion of said housing is reusable (element 1, Fig. 1 Rosenthal; Figs. 2-6 of Schulz).

In regard to claim 4, Rosenthal as modified by Schulz and Sakai discloses at least a portion of said housing is disposable (element 20, Fig. 1 Rosenthal; any replaceable parts, Figs. 2-6 of Schulz).

In regard to claim 5, Rosenthal as modified by Schulz and Sakai discloses a cable connected to a patient monitor (Figs. 1-2 and 5 and associated descriptions of Schulz) configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal).

In regard to claim 7, Rosenthal as modified by Schulz and Sakai discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 8, Rosenthal as modified by Schulz and Sakai discloses the sensor comprises a photodetector (element 28 in element 1, Fig. 1 of Rosenthal; element 260, Fig. 2 of Schulz) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal; Figs. 1-

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4 of Schulz) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal).

Rosenthal as modified by Schulz and Sakai does not specifically disclose a plurality of photodetectors. However, wavelength-specific photodetectors are well known in the art. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to substitute photodetector with wavelength-specific photodetectors to yield predictable results.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Schulz and Sakai as applied to claim 5 above, and further in view of Aronow. In regard to claim 6, Rosenthal as modified by Schulz and Sakai discloses all the claimed limitations except one of the one or more physiological parameters comprises total hemoglobin. Aronow teaches the optical monitoring system comprises light source(s) and photodetector(s) can be used to measure physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow). Total hemoglobin is also an important blood parameter. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modified the monitor (Rosenthal as modified by Schulz and Sakai) to incorporate measuring total hemoglobin (Aronow) in order to obtain more physiological information of the patient.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Schulz and Sakai as applied to claim 5 above, and further in

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view of Schmitt (USPN 6,606,509 – cited in previous action). In regard to claim 9, Rosenthal as modified by Schulz and Sakai discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Schulz and Sakai) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/ hydration information.

8. Claims 10-12, 14-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal in view of Schulz, in view of Sakai and further in view Blank et al. (USPGPUB 2004/0039271 – cited in previous action). In regard to claim 10, Rosenthal discloses a method of measuring an analyte and a temperature at a measurement site of a living patient (Fig. 1), said method comprising: emitting optical radiation on the measurement site (elements 5 and 6, Fig. 1); detecting said optical radiation after attenuation by tissue at the measurement site (element 8, Fig. 1); measuring the temperature of said measurement site (element 29, Fig. 1); using a signal processor (element 10, Fig. 1), determining an output measurement value indicative of the analyte based on the detected streams of optical radiation (glucose concentration, Col 1 lines 26-63). Rosenthal does not specifically disclose a sensor

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configuration of a clip sensor. Schulz teaches a housing forming a clip sensor (Figs. 1-6) and including: a first shell (element 210, Fig. 2; element 410, Fig. 4; element 610, Fig. 6) housing an optical source (element 250, Fig. 2; associated elements in Fig. 4); a second shell (element 240, Fig. 2; element 420, Fig. 4; element 620, Fig. 6) hinged to the first shell (Figs. 1-6) and housing said photodetector (element 260, Fig. 2); a spring disposed between and urging together the shells (element 294, Fig. 2; elements 310, Fig. 3; element 430, Fig. 4; element 630, Fig. 6). It is known that a separate sensor structure is considered as much easier for performing regular maintenances such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a separate clip sensor (Schulz) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts.

Rosenthal as modified by Schulz does not specifically disclose a heat sink integrated as a single piece with the first shell of said housing. Sakai teaches a heat sink integrated as a single piece with a sensor (element 72, Fig. 5 and associated descriptions) for radiating heat toward the outside of the sensor (Fig. 5). The light source utilized in the clip sensor structure taught by Rosenthal as modified by Schulz (Figs. 1-6 of Schulz) is enclosed by the upper shell structures. It is known that a heat sink(s) can be utilized to dispensing heat generated by light emitting sources and maintain the light sources at a moderate operating temperature as evidenced by Aronow. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made

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to modify the sensor (Rosenthal as modified by Schulz) to incorporate the use of a heat sink integrated as a single piece (Sakai) with the first shell structure which encloses the light source(s) in order to more efficiently dispensing heat toward outside of the sensor housing and obtain more stable operation performance of the light source(s). Rosenthal as modified by Schulz and Sakai does not specifically disclose determining an indication of perfusion from said temperature measurement. Blank teaches localized perfusion is important because the surface capillaries affect the amount of blood present near the skin surface ([0036]). The change can affect the optical measurement for detecting a blood analyte concentration ([0036]) and skin temperature affects perfusion ([0041]). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the method (Rosenthal as modified by Schulz and Sakai) to determine an indication of perfusion through the measurements of skin temperatures (Blank) in order to facilitate the optical detection of analyte.

In regard to claim 11, Rosenthal as modified by Schulz, Sakai, and Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal).

In regard to claim 12, Rosenthal as modified by Schulz, Sakai, and Blank discloses correcting wavelength drift after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 14, Rosenthal as modified by Schulz, Sakai, and Blank discloses a signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Fig. 1 of Rosenthal), the

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system comprising: a noninvasive optical clip type sensor (section 2, Fig. 1 of Rosenthal; Figs. 1-6 of Schulz) including: a housing forming a clip sensor and including: a first shell housing an optical source; a second shell hinged to the first shell and housing said photodetector (referring to claim 10 above); a heat sink integrated with and forming part of the first shell (referring to claim 10 above); a spring disposed between and urging together the shells (referring to claim 10 above); an optical source configured to emit optical radiation onto said tissue at said measurement site (referring to claim 10 above); at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (referring to claim 10 above) and output at least one respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal); a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 of Rosenthal); a monitor (element 10, Fig. 1 of Rosenthal; monitor, Figs. 1-6 and associated descriptions of Schultz) configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal); and a cable connected to the monitor providing communication between said optical sensor and said monitor (Fig. 1 of Schulz).

In regard to claim 15, Rosenthal as modified by Schulz, Sakai, and Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal; Figs. 1-6 and associated descriptions of Schultz).

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In regard to claim 16, Rosenthal as modified by Schulz, Sakai, and Blank discloses at least a portion of said sensor is reusable (element 1, Fig. 1 Rosenthal; Figs. 2-6 of Schulz).

In regard to claim 17, Rosenthal as modified by Schulz, Sakai, and Blank discloses at least a portion of said sensor is disposable (element 20, Fig. 1 Rosenthal; any replaceable parts, Figs. 2-6 of Schulz).

In regard to claim 19, Rosenthal as modified by Schulz, Sakai, and Blank discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 line 1 - Col 2 line 41 of Rosenthal).

In regard to claim 20, Rosenthal as modified by Schulz, Sakai, and Blank discloses the sensor comprises a photodetector (element 28 in element 1, Fig. 1 of Rosenthal) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal). Rosenthal as modified by Schulz, Sakai, and Blank does not specifically disclose a plurality of photodetectors. However, wavelength-specific photodetectors are well known in the art. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to substitute photodetector with wavelength-specific photodetectors to yield predictable results.

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9. Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Schulz, Sakai, and Blank as applied to claims 10 and 14 above, and further in view of Aronow. In regard to claims 13 and 18, Rosenthal as modified by Schulz, Sakai, and Blank discloses all the claimed limitations except one of the one or more physiological parameters comprises total hemoglobin. Aronow teaches the optical monitoring system comprises light source(s) and photodetector(s) can be used to measure physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow). Total hemoglobin is also an important blood parameter. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modified the monitor (Rosenthal as modified by Schulz, Sakai, and Blank) to incorporate measuring total hemoglobin (Aronow) in order to obtain more physiological information of the patient.

10. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Schulz, Sakai, and Blank as applied to claim 14 above, and further in view of Schmitt. In regard to claim 21, Rosenthal as modified by Schulz, Sakai, and Blank discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill

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in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Schulz, Sakai, and Blank) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/ hydration information.

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Schulz, Sakai, and Blank as applied to claim 14 above, and further in view of Al-Ali et al. (USPGPUB 2006/0220881 – cited in previous action). In regard to claim 22, Rosenthal as modified by Schulz, Sakai, and Blank discloses all the claimed limitations except said monitor comprises handheld monitor. Al-Ali teaches a handheld monitor (abstract; Figs. 2, 7 and 11A) configured to be connected to a clip style sensor ([0040]) for displaying physiological parameters. Rosenthal as modified by Schulz, Sakai, and Blank discloses a monitor (Figs. 1-2 and associated descriptions of Schulz). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the system (Rosenthal as modified by Schulz, Sakai, and Blank) to incorporate a handheld monitor (Al-Ali) in order to increase the portability of the system.

Response to Arguments

12. Applicant's amendment and argument with respect to claims 1-22 filed on 06/04/2014 have been fully considered but they are deemed to be moot in views of the new grounds of rejection.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TSE CHEN/
Supervisory Patent Examiner, Art Unit 3777

/CHU CHUAN (JJ) LIU/
Examiner, Art Unit 3777

<i>Index of Claims</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47			
CLAIM		DATE							
Final	Original	11/01/2012	04/10/2013	10/29/2013	03/25/2014	09/09/2014			
	1	✓	✓	✓	✓	✓			
	2	✓	✓	✓	✓	✓			
	3	✓	✓	✓	✓	✓			
	4	✓	✓	✓	✓	✓			
	5	✓	✓	✓	✓	✓			
	6	✓	✓	✓	✓	✓			
	7	✓	✓	✓	✓	✓			
	8	✓	✓	✓	✓	✓			
	9	✓	✓	✓	✓	✓			
	10	✓	✓	✓	✓	✓			
	11	✓	✓	✓	✓	✓			
	12	✓	✓	✓	✓	✓			
	13	✓	✓	✓	✓	✓			
	14	✓	✓	✓	✓	✓			
	15	✓	✓	✓	✓	✓			
	16	✓	✓	✓	✓	✓			
	17	✓	✓	✓	✓	✓			
	18	✓	✓	✓	✓	✓			
	19	✓	✓	✓	✓	✓			
	20	✓	✓	✓	✓	✓			
	21	✓	✓	✓	✓	✓			
	22	✓	✓	✓	✓	✓			

CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
SHEET 1 OF 2		Attorney Docket No. CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	5,043,820	08-27-1991	Wyles et al.	
	2	8,584,345	10/2013	Al-Ali et al.	
	3	8,588,880	11/2013	Abdul-Hafiz et al.	
	4	8,600,467	12/2013	Al-Ali et al.	
	5	8,606,342	12/2013	Diab	
	6	8,626,255	01/2014	Al-Ali et al.	
	7	8,630,691	01/2014	Lamego et al.	
	8	8,634,889	01/2014	Al-Ali et al.	
	9	8,641,631	02/2014	Sierra et al.	
	10	8,652,060	02/2014	Al-Ali	
	11	8,663,107	03/2014	Kiani	
	12	8,666,468	03/2014	Al-Ali	
	13	8,667,967	03/2014	Al- Ali et al.	
	14	8,670,811	03/2014	O'Reilly	
	15	8,670,814	03/2014	Diab et al.	
	16	8,676,286	03/2014	Weber et al.	
	17	8,682,407	03/2014	Al-Ali	
	18	8,690,799	04/2014	Telfort et al.	
	19	8,700,112	04/2014	Kiani	
	20	8,702,627	04/2014	Telfort et al.	
	21	8,706,179	04/2014	Parker	
	22	8,712,494	04/2015	MacNeish, III et al.	
	23	8,715,206	05/2014	Telfort et al.	
	24	8,718,735	05/2014	Lamego et al.	
	25	8,718,737	05/2014	Diab et al.	
	26	8,720,249	05/2014	Al-Ali	
	27	8,721,541	05/2014	Al-Ali et al.	
	28	8,721,542	05/2014	Al-Ali et al.	
	29	8,723,677	05/2014	Kiani	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language translation is attached. **ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/**

CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu, Chu Chuan
SHEET 2 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	8,740,792	06/2014	Kiani et al.	
	31	8,754,776	06/2014	Poeze et al.	
	32	8,755,535	06/2014	Telfort et al.	
	33	8,755,856	06/2014	Diab et al.	
	34	8,755,872	06/2014	Marinow	
	35	8,761,850	06/2014	Lamego	
	36	RE44,823	04/2014	Parker	
	37	RE44,875	04/2014	Kiani et al.	
	38	2006/0076473	04-13-2006	Wilcken et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹


NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹

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Examiner Signature	/Chu Chuan Liu/	Date Considered	09/09/2014
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

T¹ - Place a check mark in this area when an English language translation is attached.

Appx58838

Search Notes 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	04/10/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	10/29/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	03/25/2014	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	09/09/2014	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	04/10/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	10/29/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	03/25/2014	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	09/09/2014	CCL

/CHU CHUAN (JJ) LIU/
Examiner.Art Unit 3777

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/CHU CHUAN (JJ) LIU/
Examiner.Art Unit 3777

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L7	2	"20050085704"	US-PGPUB; USPAT	OR	ON	2014/09/09 15:03
S75	116	(emitting adj diode light adj source) with heat adj sink with surface with body	US-PGPUB; USPAT	OR	ON	2014/09/09 14:05
S74	9	(emitting adj diode light adj source) with heat adj sink with integrated with body	US-PGPUB; USPAT	OR	ON	2014/09/09 14:03
S73	441	(emitting adj diode light adj source) with heat adj sink with body	US-PGPUB; USPAT	OR	ON	2014/09/09 14:02
S72	229	shell and finger and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2014/09/09 11:39
S71	49	S70 and "600".clas.	US-PGPUB; USPAT	OR	ON	2014/09/09 10:08
S70	992	S69 and fin and source	US-PGPUB; USPAT	OR	ON	2014/09/09 10:07
S69	3829	(clip shell) and finger and heat with sink	US-PGPUB; USPAT	OR	ON	2014/09/09 10:07
S68	2	S67 and heat with sink	US-PGPUB; USPAT	OR	ON	2014/09/09 09:59
S67	37	("20060076473" "5043820" "8584345" "8600467" "8606342" "8626255" "8630691" "8634889" "8641631" "8652060" "8663107" "8666468" "8667967" "8670811" "8670814" "8676283" "8682407" "8690799" "8700112" "8702627" "8706179" "8712494" "8715206" "8718735" "8718737" "8720249" "8721541" "8721542" "8723677" "8740792" "8754776" "8755535" "8755856" "8755872" "8761850" "RE44823" "RE44875").PN.	US-PGPUB; USPAT	OR	ON	2014/09/09 09:59
S66	27	heat adj sink with fin and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2014/09/09 09:54

EAST Search History (Interference)

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9/ 9/ 2014 4:36:52 PM

EAST Search History

CX-1622

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Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

CX-1622
PTO/SB/30EFS (07-09)

Approved for use through 07/31/2012. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)**

Application Number	12829352	Filing Date	2010-07-01	Docket Number (if applicable)	CERCA.002C1	Art Unit	3777
First Named Inventor	Jeroen Poeze			Examiner Name	Liu, Chu Chuan		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____☒ Other Response to Final Office Action previously filed on June 4, 2014☒ Enclosed☐ Amendment/Reply☒ Information Disclosure Statement (IDS)☐ Affidavit(s)/ Declaration(s)☐ Other _____**MISCELLANEOUS**☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)☐ Other _____**FEES****The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 111410**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**☒ Patent Practitioner Signature☐ Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

CX-1622

PTO/SB/30EFS (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Signature of Registered U.S. Patent Practitioner			
Signature	/Jarom Kesler/	Date (YYYY-MM-DD)	2014-06-27
Name	Jarom Kesler	Registration Number	57046

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Jarom D. Kesler/Stacy Ho			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
RCE - 2nd and Subsequent Request	1820	1	1700	1700
Total in USD (\$)				1700

CX-1622

Electronic Acknowledgement Receipt

EFS ID:	19441973
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Jarom D. Kesler/Gustavo Lopez
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	CERCA.002C1
Receipt Date:	27-JUN-2014
Filing Date:	01-JUL-2010
Time Stamp:	20:03:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1700
RAM confirmation Number	7452
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

Page 570 of 1082

Appx58848

CX-1622

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CERCA_002C1_IDS.pdf	52345 294df765595a413ae9515bced33294bce250b5d5	yes	3
Multipart Description/PDF files in .zip description					
	Document Description		Start	End	
	Transmittal Letter		1	1	
	Information Disclosure Statement (IDS) Form (SB08)		2	3	
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	CERCA_002C1_RCE.pdf	697922 9d84171a4224c8e1de1c6f98c02dfa15ff30b95e	no	3
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30291 e0e1a2283a27a10bd538374e06a1539182e1dc2	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			780558		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Docket No.: CERCA.002C1

Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

Inventor	:	Jeroen Poeze
App. No.	:	12/829352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf. No.	:	8366

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed within three months of the filing date or date of national phase entry, with an RCE or before receipt of a First Office Action after an RCE, and no fee is required.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 27, 2014

By: /Jarom Kesler/

Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

18308727

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu, Chu Chuan
SHEET 1 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	5,043,820	08-27-1991	Wyles et al.	
	2	8,584,345	10/2013	Al-Ali et al.	
	3	8,588,880	11/2013	Abdul-Hafiz et al.	
	4	8,600,467	12/2013	Al-Ali et al.	
	5	8,606,342	12/2013	Diab	
	6	8,626,255	01/2014	Al-Ali et al.	
	7	8,630,691	01/2014	Lamego et al.	
	8	8,634,889	01/2014	Al-Ali et al.	
	9	8,641,631	02/2014	Sierra et al.	
	10	8,652,060	02/2014	Al-Ali	
	11	8,663,107	03/2014	Kiani	
	12	8,666,468	03/2014	Al-Ali	
	13	8,667,967	03/2014	Al- Ali et al.	
	14	8,670,811	03/2014	O'Reilly	
	15	8,670,814	03/2014	Diab et al.	
	16	8,676,286	03/2014	Weber et al.	
	17	8,682,407	03/2014	Al-Ali	
	18	8,690,799	04/2014	Telfort et al.	
	19	8,700,112	04/2014	Kiani	
	20	8,702,627	04/2014	Telfort et al.	
	21	8,706,179	04/2014	Parker	
	22	8,712,494	04/2015	MacNeish, III et al.	
	23	8,715,206	05/2014	Telfort et al.	
	24	8,718,735	05/2014	Lamego et al.	
	25	8,718,737	05/2014	Diab et al.	
	26	8,720,249	05/2014	Al-Ali	
	27	8,721,541	05/2014	Al-Ali et al.	
	28	8,721,542	05/2014	Al-Ali et al.	
	29	8,723,677	05/2014	Kiani	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English Language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu, Chu Chuan
SHEET 2 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	8,740,792	06/2014	Kiani et al.	
	31	8,754,776	06/2014	Poeze et al.	
	32	8,755,535	06/2014	Telfort et al.	
	33	8,755,856	06/2014	Diab et al.	
	34	8,755,872	06/2014	Marinow	
	35	8,761,850	06/2014	Lamego	
	36	RE44,823	04/2014	Parker	
	37	RE44,875	04/2014	Kiani et al.	
	38	2006/0076473	04-13-2006	Wilcken et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹

18307734

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English Language Translation is attached.

CX-1622

PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		<input type="checkbox"/> To be Mailed	
Substitute for Form PTO-875				12/829,352		07/01/2010			
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL					
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	06/27/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE						0			
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE									
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	06/20/2014
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
06/20/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Advisory Action Before the Filing of an Appeal Brief	Application No. 12/829,352		Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU		Art Unit 3777	AIA (First Inventor to File) Status No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2014 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.
NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires _____ months from the mailing date of the prior Advisory Action or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because

a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

b) ☐ They raise the issue of new matter (see NOTE below);

c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): (a) ☒ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

14. ☒ Other: See Continuation Sheet.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-22.

Claim(s) withdrawn from consideration: _____

/TSE CHEN/ Supervisory Patent Examiner, Art Unit 3777	/CHU CHUAN (JJ) LIU/ Examiner, Art Unit 3777
--	---

Continuation Sheet (PTOL-303)

Application No. 12/829,352 CX-1622

Continuation of 3. NOTE: The amendments change the scope of the claims and therefore require further consideration and/ or search.

Continuation of 11. does NOT place the application in condition for allowance because: The amendments change the scope of the claims and therefore require further consideration and/ or search.

Continuation of 14. Other: Applicant's request for entry into AFCP 2.0 is acknowledged, but is denied because the response cannot be reviewed and a search conducted in the limited amount of time authorized for this pilot program. Therefore, the response is being reviewed under pre-pilot practice..

DO NOT ENTER: /CCL/

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	: Jeroen Poeze
App. No.	: 12/829352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf. No.	: 8366

RESPONSE TO FINAL OFFICE ACTION DATED APRIL 4, 2014

AND

**REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION
PILOT PROGRAM 2.0**

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Final Office Action dated April 4, 2014, Applicant respectfully submits the following amendment and comments in connection with the above-captioned application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Summary of Interview begins on page 6 of this paper.

Remarks/Arguments begin on page 7 of this paper.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
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 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	06/13/2014
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
06/13/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	

All participants (applicant, applicant's representative, PTO personnel):

(1) Chu Chuan Liu. (3) Jarom Kesler.

(2) Robert Chen. (4) ____.

Date of Interview: 04 June 2014.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: ____.

Issues Discussed ☐ 101 ☐ 112 ☐ 102 ☒ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: Aronow (USPN 5,851,178).

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

During the interview, claim 1 and Figs. 2-3 of Aronow were discussed. Examiner explained how the heat sink and corresponding structures meet the limitations of "integrated with a forming part of the first shell". Suggested languages include "forming one piece" and/ or "not separable" were discussed. Attorney indicated a formal response will be filed. Examiner indicated that an updated search is required when the formal response has been filed.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/CHU CHUAN (JJ) LIU/ Examiner, Art Unit 3777	/TSE CHEN/ Supervisory Patent Examiner, Art Unit 3777
---	--

Summary of Record of Interview Requirements**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Doc Code: A.NE.AFCP

Document Description: After Final Consideration Pilot Program Request

PTO/SB/434 (05-13)

CERTIFICATION AND REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0		
Practitioner Docket No.: CERCA.002C1	Application No.: 12/829352	Filing Date: July 1, 2010
First Named Inventor: Jeroen Poeze	Title: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	
<p>APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION PILOT PROGRAM 2.0 (AFCP 2.0) OF THE ACCOMPANYING RESPONSE UNDER 37 CFR 1.116.</p> <ol style="list-style-type: none"> 1. The above-identified application is (i) an original utility, plant, or design nonprovisional application filed under 35 U.S.C. 111(a) [a continuing application (<i>e.g.</i>, a continuation or divisional application) is filed under 35 U.S.C. 111(a) and is eligible under (i)], or (ii) an international application that has entered the national stage in compliance with 35 U.S.C. 371(c). 2. The above-identified application contains an outstanding final rejection. 3. Submitted herewith is a response under 37 CFR 1.116 to the outstanding final rejection. The response includes an amendment to at least one independent claim, and the amendment does not broaden the scope of the independent claim in any aspect. 4. This certification and request for consideration under AFCP 2.0 is the only AFCP 2.0 certification and request filed in response to the outstanding final rejection. 5. Applicant is willing and available to participate in any interview requested by the examiner concerning the present response. 6. This certification and request is being filed electronically using the Office's electronic filing system (EFS-Web). 7. Any fees that would be necessary consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, extension of time fees, are being concurrently filed herewith. [There is no additional fee required to request consideration under AFCP 2.0.] 8. By filing this certification and request, applicant acknowledges the following: <ul style="list-style-type: none"> • Reissue applications and reexamination proceedings are not eligible to participate in AFCP 2.0. • The examiner will verify that the AFCP 2.0 submission is compliant, <i>i.e.</i>, that the requirements of the program have been met (see items 1 to 7 above). For compliant submissions: <ul style="list-style-type: none"> ○ The examiner will review the response under 37 CFR 1.116 to determine if additional search and/or consideration (i) is necessitated by the amendment and (ii) could be completed within the time allotted under AFCP 2.0. If additional search and/or consideration is required but cannot be completed within the allotted time, the examiner will process the submission consistent with current practice concerning responses after final rejection under 37 CFR 1.116, <i>e.g.</i>, by mailing an advisory action. ○ If the examiner determines that the amendment does not necessitate additional search and/or consideration, or if the examiner determines that additional search and/or consideration is required and could be completed within the allotted time, then the examiner will consider whether the amendment places the application in condition for allowance (after completing the additional search and/or consideration, if required). If the examiner determines that the amendment does not place the application in condition for allowance, then the examiner will contact the applicant and request an interview. <ul style="list-style-type: none"> ▪ The interview will be conducted by the examiner, and if the examiner does not have negotiation authority, a primary examiner and/or supervisory patent examiner will also participate. ▪ If the applicant declines the interview, or if the interview cannot be scheduled within ten (10) calendar days from the date that the examiner first contacts the applicant, then the examiner will proceed consistent with current practice concerning responses after final rejection under 37 CFR 1.116. 		
Signature /Jarom Kesler/	Date 2014-06-04	
Name (Print/Typed) Jarom D. Kesler	Practitioner Registration No. 57,046	
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.		
<input checked="" type="checkbox"/> * Total of <u>1</u> forms are submitted.		

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	: Jeroen Poeze
App. No.	: 12/829352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf. No.	: 8366

RESPONSE TO FINAL OFFICE ACTION DATED APRIL 4, 2014

AND

**REQUEST FOR CONSIDERATION UNDER THE AFTER FINAL CONSIDERATION
PILOT PROGRAM 2.0**

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Final Office Action dated April 4, 2014, Applicant respectfully submits the following amendment and comments in connection with the above-captioned application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Summary of Interview begins on page 6 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Application No.: 12/829352
Filing Date: July 1, 2010

AMENDMENTS TO THE CLAIMS

A complete listing of all claims is presented below with insertions underline (e.g., insertion), and deletions struck through or in double brackets (e.g., ~~deletion~~ or [[deletion]]).

1. (Currently Amended) A noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:
 - an optical source configured to emit optical radiation onto said tissue at said measurement site;
 - at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;
 - a housing positioning said optical source and said at least one photodetector with respect to said measurement site, said housing forming a clip sensor and including:
 - a first shell housing said optical source;
 - a second shell hinged to the first shell and housing said photodetector;
 - a spring disposed between and urging together the shells;
 - a heat sink integrated ~~with and forming part of~~ as a single piece of with the first shell of said housing; and
 - a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site.
2. (Original) The sensor of claim 1, wherein said tissue at said measurement site comprises a digit of said patient.
3. (Original) The sensor of claim 1, wherein at least a portion of said housing is reusable.
4. (Original) The sensor of claim 1, wherein at least a portion of said housing is disposable.
5. (Previously Presented) The sensor of claim 1, comprising a cable connected to a patient monitor configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters.

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Filing Date: July 1, 2010

6. (Original) The sensor of claim 5, wherein one of the one or more physiological parameters comprises total hemoglobin.

7. (Original) The sensor of claim 5, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

8. (Original) The sensor of claim 1, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

9. (Original) The sensor of claim 1, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

10. (Currently Amended) A method of measuring an analyte and a temperature at a measurement site of a living patient, said method comprising:

emitting optical radiation on the measurement site from a first shell of a clip-type sensor;

detecting said optical radiation after attenuation by tissue at the measurement site in a second shell of the clip-type sensor, the first shell hinged to the second shell;

dissipating heat from the first shell using a heat sink integrated with and forming part of a single piece with the first shell;

measuring the temperature of said measurement site;

using a signal processor, determining an indication of perfusion from said temperature measurement; and

determining an output measurement value indicative of the analyte based on the detected streams of optical radiation.

11. (Previously Presented) The method of claim 10, wherein said tissue at said measurement site comprises a digit of said patient.

12. (Previously Presented) The method of claim 10, wherein the method further comprises correcting wavelength drift after attenuation by said tissue.

13. (Previously Presented) The method of claim 10, wherein said analyte comprises total hemoglobin.

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Filing Date: July 1, 2010

14. (Currently Amended) A signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the system comprising:

a noninvasive clip-type optical sensor including:

a housing including a first shell, a second shell hinged to the first shell and a spring disposed between and urging together the shells;

an optical source configured to emit optical radiation onto said tissue at said measurement site and housed in the first shell;

a heat sink integrated ~~with and forming part of~~ a single piece with the first shell;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation, the at least one photodetector housed in the second shell;

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site;

a monitor configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters; and

a cable connected to the monitor providing communication between said optical sensor and said monitor.

15. (Original) The system of claim 14, wherein said tissue at said measurement site comprises a digit of said patient.

16. (Original) The system of claim 14, wherein at least a portion of said sensor is reusable.

17. (Original) The system of claim 14, wherein at least a portion of said sensor is disposable.

18. (Original) The system of claim 14, wherein one of the one or more physiological parameters comprises total hemoglobin.

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Filing Date: July 1, 2010

19. (Original) The system of claim 14, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

20. (Original) The system of claim 14, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

21. (Original) The system of claim 14, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

22. (Previously Presented) The system of claim 14, wherein said monitor comprises a handheld monitor.

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Filing Date: July 1, 2010

SUMMARY OF EXAMINER INTERVIEW

The Applicants thank Examiners Liu and Supervisor Chen for the telephonic *Examiner Interview* extended to the Applicant on June 4, 2014. The following is a summary of the discussion.

Participants

For the Patent Office:

Examiner Liu and Supervisor Chen

For the Applicant:

Jarom D. Kesler, Reg. No. 57,046

Prior Art Discussed

U.S. Pat. No. 5,851,178 (Aronow)

Results of Interview

Agreement was reached that Aronow did not teach a heat sink integrated with a first shell of a sensor, however, Examiner Liu and Supervisor Chen suggested amending the language of “a heat sink integrated with and forming part of the first shell” to “a heat sink integrated as a single piece with the first shell” in order to clarify the claimed subject matter. Although Applicant disagreed that the language change was necessary, Applicant agreed to make the change in order to progress examination of the present application.

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Filing Date: July 1, 2010

REMARKS

By way of summary, Claims 1-22 were pending in this application. In the present amendment, the Applicants have amended Claims 1, 10, and 14, and 11. Accordingly, Claims 1-22 remain pending for consideration.

Interview

Applicants thank the Examiners for the courtesy of the interview extended after final. During the *Examiner Interview* summarized in the foregoing, the Applicant clarified patentably distinguishing features and an agreement was reached relating to claim language. Accordingly, the Applicant amends the claims herein along the lines discussed in the interview. Therefore, the Applicants respectfully request reconsideration of the pending amended claims.

Rejection Of Claims 1-8 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1-8 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,362,966, issued to Rosenthal, (the Rosenthal patent) in view of U.S. Pat. No. 5,851,178, issued to Aronow, (the 5,851,178 patent). The Applicants respectfully traverse this rejection for the following reasons.

Claim 1 recites, *inter alia*, “a heat sink integrated as a single piece with the first shell of said housing”. An embodiment of Claim 1 is shown, for example, in Fig. 2B, reproduced below. The heat sink is integrated as a single piece with the first shell.

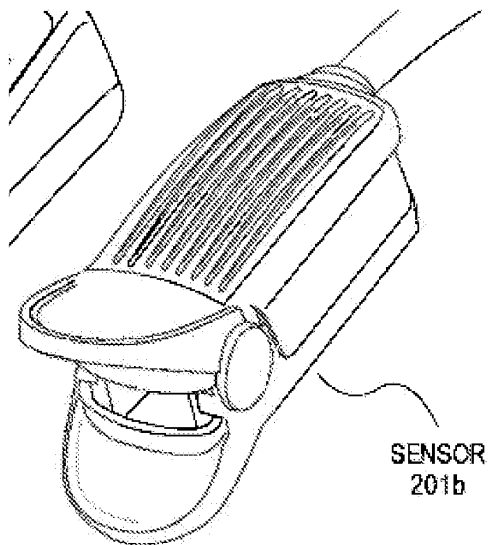
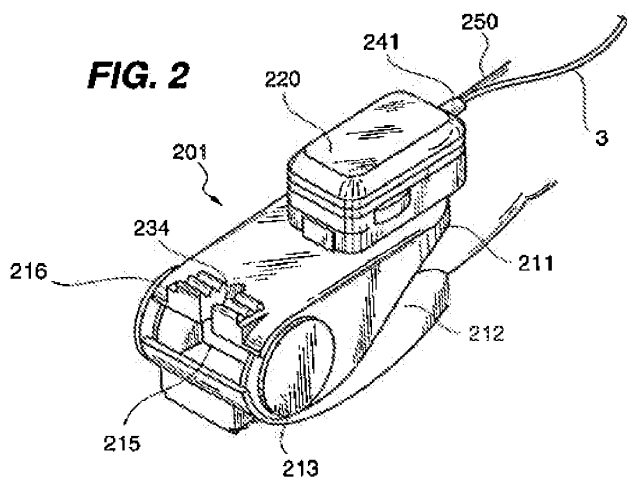


FIG. 2B

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Filing Date: July 1, 2010

In contrast Aronow discloses a housing 220 separate from clip sensor shells 211, 212. Aronow provides no specific disclosure of what is included in housing 220 or whether it includes a heat sink. Rather, a heat sink is only disclosed with respect to cable connector 82, described with respect to the disposable, non-clip type sensor of Figures 4-9. Thus, Aronow does not disclose a heat sink connected a clip type sensor.



Even if Aronow was construed to imply that a connector 82 is the same as housing 220 of Fig. 2, which it should not, Aronow would still fail to disclose a heat sink integrated with the first shell of the housing that forms part of the clip sensor. Rather, Aronow, at best, discloses that the heat sink is in a separate housing from the clip sensor housings. Thus, Aronow fails to disclose at least this limitation. Rosenthal does not disclose any type of clip sensor housing. Thus, the combination of Aronow and Rosenthal fail to disclose the limitations of Claim 1.

Claims 2-8 which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Rejection Of Claim 9 Under 35 U.S.C. § 103(a)

The Office Action rejected Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal in view of Aronow, and further in view of U.S. Pat. No. 6,606,509, issued to Schmitt (the Schmitt patent). The Applicants respectfully traverse this rejection for the following reasons. Claim 9 which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

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Rejection Of Claims 10-20 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1-8 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Aronow, and further in view of U.S. Pat. Pub. No. 2004/0039271 by Blank. The Applicants respectfully traverse this rejection for the following reasons. Independent Claims 10 and 14 include limitations similar to that discussed above with respect to Claim 1. Specifically, that a heat sink is integrated with a first shell of a clip type sensor. As discussed above, Aronow fails to teach or disclose such a limitation. Rosenthal and Blank are cited for other reasons and also fail to disclose at least this limitation. Thus, for the same reasons discussed above with respect to Claim 1, Applicants respectfully request the rejection of Claims 10 and 14 be withdrawn.

Claims 11-13 and 15-20 which depend from either Claims 10 or 14 are believed to be patentable for the same reasons articulated above with respect to Claims 10 and 14, and because of the additional features recited therein.

Rejection Of Claim 21 Under 35 U.S.C. § 103(a)

The Office Action rejected Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal in view of Aronow and Schmitt. The Applicants respectfully traverse this rejection for the following reasons. Claim 21 which depends from Claim 14, is believed to be patentable for the same reasons articulated above with respect to Claim 14, and because of the additional features recited therein.

Rejection Of Claim 22 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 22 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal in view of Aronow, Blank and US Patent Publication No. 2006/0220881 by Al-Ali. The Applicants respectfully traverse this rejection for the following reasons. Claim 22 which depends from Claim 14, is believed to be patentable for the same reasons articulated above with respect to Claim 14, and because of the additional features recited therein.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

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Filing Date: July 1, 2010

application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
CERCA.002A	12/534827	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	08/03/2009
CERCA.003D1	14/153895	MULTI-STREAM SENSOR FRONT ENDS FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	01/13/2014
CERCA.004C3	14/064055	MULTI-STREAM SENSOR FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	10/25/2013
CERCA.006C1	14/069974	NOISE SHIELDING FOR A NONINVAISE DEVICE	11/01/2013
CERCA.007C1	13/888266	CONTOURED PROTRUSION FOR IMPROVING SPECTROSCOPIC MEASUREMENT OF BLOOD CONSTITUENTS	05/06/2013
CERCA.008C1	14/227230	EMITTER DRIVER FOR NONINVASIVE PATIENT MONITOR	03/27/2014
CERCA.011A	12/497506	HEAT SINK FOR NONINVASIVE MEDICAL SENSOR	07/02/2009

Application No.: 12/829352
Filing Date: July 1, 2010

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 4, 2014

By:...../Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

17981599

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	19214344
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Jarom D. Kesler/Mason Leu
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	CERCA.002C1
Receipt Date:	04-JUN-2014
Filing Date:	01-JUL-2010
Time Stamp:	18:59:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	After Final Consideration Program Request	reqforcon.PDF	227010 346822265a6f4e3468dc45a10f35c183952e a2f9	no	2

Warnings:**Information:**

CX-1622

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	Multipart Description/PDF files in .zip description										
	Document Description		Start	End							
	Response After Final Action		1	1							
	Claims		2	5							
	Applicant summary of interview with examiner		6	6							
	Applicant Arguments/Remarks Made in an Amendment		7	11							
Warnings:											
Information:											
Total Files Size (in bytes):			1050494								
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CX-1622

PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		<input type="checkbox"/> To be Mailed	
Substitute for Form PTO-875				12/829,352		07/01/2010			
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL					
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	06/04/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE						0			
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE									
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	04/04/2014
KNOBBE MARTENS OLSON & BEAR LLP		
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IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
04/04/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Office Action Summary	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 02/05/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-22 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☒ Claim(s) 1-22 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 02/05/2014.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

Appx58878

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DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. Applicant's amendments/ remarks filed on 02/05/2014 have been fully considered.
3. Claims 1-22 are pending for examination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (USPN 5,362,966 - cited in previous action) in view of Aronow (USPN 5,851,178 - cited in previous action). In regard to claim 1, Rosenthal discloses a noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Col 1 line 1 - Col 2 line 41 and Fig. 1), the sensor comprising: an optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15) configured to emit optical radiation onto said tissue at said measurement site (Fig. 1); at least one photodetector (element 8, Fig. 1) configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (Fig. 1)

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and output at least one respective signal stream responsive to said detected optical radiation (through connection between element 8 and processor 10, Fig. 1); a housing positioning said optical source and said at least one photodetector with respect to said measurement site (element 28 in element 1, Fig. 1); a thermistor (element 29, Fig. 1) operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 and Col 2 lines 25-41). Rosenthal does not specifically said housing forming a clip sensor and including: a first shell housing said optical source; a second shell hinged to the first shell and housing said photodetector; a spring disposed between and urging together the shells; and a heat sink operably connected to the first shell of said housing. Aronow teaches a housing forming a clip sensor (Figs. 1-4) and including: a first shell (element 211 and 220, Figs. 2-3) housing an optical source (elements 416, Fig. 4); a second shell (element 212, Fig. 3) hinged to the first shell (Fig. 3) and housing said photodetector (element 333, Fig. 3); a spring disposed between and urging together the shells (element 314, Fig. 3); and a heat sink integrated with and forming part of the first shell of said housing (heat sinks 414 and 415, Fig. 4. The heat sinks is integrated with the first shell and forming part of the first shell when connected to the sensor, Figs. 2-4). It is known that a separate sensor structure is considered as much easier for performing regular maintenances such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a separate clip

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sensor (Aronow) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts.

In regard to claim 2, Rosenthal as modified by Aronow discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and Fig. 2 of Aronow).

In regard to claim 3, Rosenthal as modified by Aronow discloses at least a portion of said housing is reusable (element 1, Fig. 1 Rosenthal; Figs. 2-4 of Aronow).

In regard to claim 4, Rosenthal as modified by Aronow discloses at least a portion of said housing is disposable (element 20, Fig. 1 Rosenthal; elements 321, Fig. 3 of Aronow).

In regard to claim 5, Rosenthal as modified by Aronow discloses a cable connected to a patient monitor (Fig. 1 of Aronow) configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal).

In regard to claim 6, Rosenthal as modified by Aronow discloses one of the one or more physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow).

In regard to claim 7, Rosenthal as modified by Aronow discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 8, Rosenthal as modified by Aronow discloses the sensor comprises a photodetector (element 28 in element 1, Fig. 1 of Rosenthal) configured to

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detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal). Rosenthal as modified by Aronow does not specifically disclose a plurality of photodetectors. However, wavelength-specific photodetectors are well known in the art. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to substitute photodetector with wavelength-specific photodetectors to yield predictable results.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal and Aronow as applied to claim 5 above, and further in view of Schmitt (USPN 6,606,509 – cited in previous action). In regard to claim 9, Rosenthal as modified by Aronow discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Aronow) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/hydration information.

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7. Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal in view of Aronow and further in view Blank et al. (USPGPUB 2004/0039271 – cited in previous action). In regard to claim 10, Rosenthal discloses a method of measuring an analyte and a temperature at a measurement site of a living patient (Fig. 1), said method comprising: emitting optical radiation on the measurement site (elements 5 and 6, Fig. 1); detecting said optical radiation after attenuation by tissue at the measurement site (element 8, Fig. 1); measuring the temperature of said measurement site (element 29, Fig. 1); using a signal processor (element 10, Fig. 1), determining an output measurement value indicative of the analyte based on the detected streams of optical radiation (glucose concentration, Col 1 lines 26-63). Rosenthal does not specifically disclose a sensor configuration of a clip sensor. Aronow teaches a housing forming a clip sensor (Figs. 1-4) and including: a first shell (element 211 and 220, Figs. 2-3) housing an optical source (elements 416, Fig. 4); a second shell (element 212, Fig. 3) hinged to the first shell (Fig. 3) and housing said photodetector (element 333, Fig. 3); a spring disposed between and urging together the shells (element 314, Fig. 3); and a heat sink integrated with and forming part of the first shell of said housing (heat sinks 414 and 415, Fig. 4). The heat sinks is integrated with the first shell and forming part of the first shell when connected to the sensor, Figs. 2-4). It is known that a separate sensor structure is considered as much easier for performing regular maintenances such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of

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the invention was made to modify the sensor (Rosenthal) to incorporate a separate clip sensor (Aronow) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts. Rosenthal as modified by Aronow does not specifically disclose determining an indication of perfusion from said temperature measurement. Blank teaches localized perfusion is important because the surface capillaries affect the amount of blood present near the skin surface ([0036]). The change can affect the optical measurement for detecting a blood analyte concentration ([0036]) and skin temperature affects perfusion ([0041]). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the method (Rosenthal as modified by Aronow) to determine an indication of perfusion through the measurements of skin temperatures (Blank) in order to facilitate the optical detection of analyte.

In regard to claim 11, Rosenthal as modified by Aronow and Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal).

In regard to claim 12, Rosenthal as modified by Aronow and Blank discloses correcting wavelength drift after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 13, Rosenthal as modified by Aronow and Blank discloses said analyte comprises total hemoglobin (Col 2 lines 11-23 of Aronow)

In regard to claim 14, Rosenthal as modified by Aronow and Blank discloses a signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Fig. 1 of Rosenthal), the system

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comprising: a noninvasive optical clip type sensor (section 2, Fig. 1 of Rosenthal; Figs. 2-4 of Aronow) including: a housing forming a clip sensor (Figs. 1-4 of Aronow) and including: a first shell (element 211 and 220, Figs. 2-3) housing an optical source (elements 416, Fig. 4 of Aronow); a second shell (element 212, Fig. 3 of Aronow) hinged to the first shell (Fig. 3 of Aronow) and housing said photodetector (element 333, Fig. 3 of Aronow); a heat sink integrated with and forming part of the first shell (heat sinks 414 and 415, Fig. 4. The heat sinks is integrated with the first shell and forming part of the first shell when connected to the sensor, Figs. 2-4); a spring disposed between and urging together the shells (element 314, Fig. 3 of Aronow); an optical source configured to emit optical radiation onto said tissue at said measurement site (elements 5 and 6, Fig. 1 of Rosenthal; Figs. 2-4 of Aronow); at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (element 8, Fig. 1 of Rosenthal) and output at least one respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal); a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 of Rosenthal); a monitor (element 10, Fig. 1 of Rosenthal and element 2, Figs. Fig. 1 of Aronow) configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal); and a cable connected to the monitor providing communication between said optical sensor and said monitor (Fig. 1 of Aronow).

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In regard to claim 15, Rosenthal as modified by Aronow and Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and Fig. 2 of Aronow).

In regard to claim 16, Rosenthal as modified by Aronow and Blank discloses at least a portion of said sensor is reusable (element 1, Fig. 1 Rosenthal; Figs. 2-4 of Aronow).

In regard to claim 17, Rosenthal as modified by Aronow and Blank discloses at least a portion of said sensor is disposable (element 20, Fig. 1 Rosenthal; elements 321, Fig. 3 of Aronow).

In regard to claim 18, Rosenthal as modified by Aronow and Blank discloses one of the one or more physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow).

In regard to claim 19, Rosenthal as modified by Aronow and Blank discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 line 1 - Col 2 line 41 of Rosenthal).

In regard to claim 20, Rosenthal as modified by Aronow and Blank discloses the sensor comprises a photodetector (element 28 in element 1, Fig. 1 of Rosenthal) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal). Rosenthal as modified by Aronow and Blank does

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not specifically disclose a plurality of photodetectors. However, wavelength-specific photodetectors are well known in the art. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to substitute photodetector with wavelength-specific photodetectors to yield predictable results.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Aronow and Blank as applied to claim 14 above, and further in view of Schmitt. In regard to claim 21, Rosenthal as modified by Aronow and Blank discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Aronow and Blank) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/hydration information.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Aronow and Blank as applied to claim 14 above, and further in view of Al-Ali et al. (USPGPUB 2006/0220881 – cited in previous action). In regard to claim 22, Rosenthal as modified by Aronow and Blank discloses all the claimed

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limitations except said monitor comprises handheld monitor. Al-Ali teaches a handheld monitor (abstract; Figs. 2, 7 and 11A) configured to be connected to a clip style sensor ([0040]) for displaying physiological parameters. Rosenthal as modified by Aronow and Blank discloses a monitor (Fig. 1 of Aronow). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the system (Rosenthal as modified by Aronow and Blank) to incorporate a handheld monitor (Al-Ali) in order to increase the portability of the system.

Response to Arguments

10. Applicant's arguments, see page 6 of Remarks, filed on 02/05/2014, with respect to claim 22 have been fully considered and are persuasive. The objection of claim 22 has been withdrawn.

11. Applicant's arguments filed on 02/05/2014 have been fully considered but they are not persuasive. In the remarks, Applicant alleged that Aronow does not teach or suggest "a heat sink integrated with and forming part of the first shell". However, Aronow teaches using heat sinks to dissipate heat generated by the light sources in the connector. When the connector is connected to the first shell of the probe, the heat sinks are considered as being integrated with the first shell and forming a part of the first shell (see Fig. 2). Furthermore, Aronow also teaches the number of light sources is equal to or greater than the number of blood analytes that are to be measured (Col 5 lines 23-43). There are limited areas and elements connected to the light sources and not in direct contact with the finger. One ordinary would seek for other possible heat

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sink/ probe designs (e.g. The fin heat sink are utilized in the body of the probe, Sakai et al. ,USPN 5,131,391 – applicant cited) when more light sources are used.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/CHU CHUAN (JJ) LIU/
Examiner, Art Unit 3777

/TSE CHEN/

Supervisory Patent Examiner, Art Unit 3777

Search Notes 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	04/10/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	10/29/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	03/25/2014	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	04/10/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	10/29/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	03/25/2014	CCL


INTERFERENCE SEARCH

/CHU CHUAN (JJ) LIU/ Examiner.Art Unit 3777	
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CX-1622

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/CHU CHUAN (JJ) LIU/
Examiner,Art Unit 3777

<i>Index of Claims</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant						<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47	
CLAIM		DATE									
Final	Original	11/01/2012	04/10/2013	10/29/2013	03/25/2014						
	1	✓	✓	✓	✓						
	2	✓	✓	✓	✓						
	3	✓	✓	✓	✓						
	4	✓	✓	✓	✓						
	5	✓	✓	✓	✓						
	6	✓	✓	✓	✓						
	7	✓	✓	✓	✓						
	8	✓	✓	✓	✓						
	9	✓	✓	✓	✓						
	10	✓	✓	✓	✓						
	11	✓	✓	✓	✓						
	12	✓	✓	✓	✓						
	13	✓	✓	✓	✓						
	14	✓	✓	✓	✓						
	15	✓	✓	✓	✓						
	16	✓	✓	✓	✓						
	17	✓	✓	✓	✓						
	18	✓	✓	✓	✓						
	19	✓	✓	✓	✓						
	20	✓	✓	✓	✓						
	21	✓	✓	✓	✓						
	22	✓	✓	✓	✓						

EAST Search History

CX-1622

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L8	1	("5,891,022").PN.	US-PGPUB; USPAT	OR	OFF	2014/03/25 10:02
L7	69	heat adj sink\$1 and finger and (600/310-344 356/41).ccls.	US-PGPUB; USPAT	OR	ON	2014/03/25 09:55
L6	24	heat adj sink\$1 and finger and clip and (600/310-344 356/41).ccls.	US-PGPUB; USPAT	OR	ON	2014/03/25 09:54

EAST Search History (Interference)

< This search history is empty >

3/ 25/ 2014 10:44:16 AM**C:\ Users\ cliu\ Documents\ EAST\ Workspaces\ 12829352.wsp**

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze, et al.
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu, Chu Chuan
SHEET 1 OF 3	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	5,043,820	08/1991	Wyles et al.	
	2	5,427,093	06-1995	Ogawa et al.	
	3	6,278,889	08-2001	Robinson	
	4	6,995,400	02-2006	Mizuyoshi	
	5	7,509,153	03-2009	Blank et al.	
	6	7,734,320	06-2012	Al-Ali	
	7	8,233,955	07/2012	Al-Ali et al.	
	8	8,244,325	08/2012	Al-Ali et al.	
	9	8,255,026	08/2012	Al-Ali	
	10	8,255,027	08/2012	Al-Ali et al.	
	11	8,255,028	08/2012	Al-Ali et al.	
	12	8,260,577	09/2012	Weber et al.	
	13	8,265,723	09/2012	McHale et al.	
	14	8,274,360	09/2012	Sampath et al.	
	15	8,301,217	10/2012	Al-Ali et al.	
	16	8,310,336	11/2012	Muhsin et al.	
	17	8,315,683	11/2012	Al-Ali et al.	
	18	8,337,403	12/2012	Al-Ali et al.	
	19	8,346,330	01/2013	Lamego	
	20	8,353,842	01/2013	Al-Ali et al.	
	21	8,355,766	01/2013	MacNeish, III et al.	
	22	8,359,080	01/2013	Diab et al.	
	23	8,364,223	01/2013	Al-Ali et al.	
	24	8,364,226	01/2013	Diab et al.	
	25	8,374,665	02/2013	Lamego	
	26	8,385,995	02/2013	Al-ali et al.	
	27	8,385,996	02/2013	Smith et al.	
	28	8,388,353	03/2013	Kiani et la.	
	29	8,399,822	03/2013	Al-Ali	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language translation is attached. **ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/**

CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
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	31	8,405,608	03/2013	Al-Ali et al.	
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	33	8,418,524	04/2013	Al-Ali	
	34	8,423,106	04/2013	Lamego et al.	
	35	8,428,967	04/2013	Olsen et al.	
	36	8,430,817	04/2013	Al-Ali et al.	
	37	8,437,825	05-2013	Dalvi et al.	
	38	8,437,825	05/2013	Dalvi et al.	
	39	8,455,290	06/2013	Siskavich	
	40	8,457,703	06/2013	Al-Ali	
	41	8,457,707	06/2013	Kiani	
	42	8,463,349	06/2013	Diab et al.	
	43	8,466,286	06/2013	Bellot et al.	
	44	8,471,713	06/2013	Poeze et al.	
	45	8,473,020	06/2013	Kiani et al.	
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	48	8,498,684	07/2013	Weber et al.	
	49	8,509,867	08/2013	Workman et al.	
	50	8,515,509	08-2013	Bruinsma et al.	
	51	8,515,509	08/2013	Bruinsma et al.	
	52	8,523,781	09/2013	Al-Ali	
	53	8,529,301	09/2013	Al-Ali et al.	
	54	8,532,727	09/2013	Ali et al.	
	55	8,532,728	09/2013	Diab et al.	
	56	8,547,209	10/2013	Kiani et al.	
	57	8,548,548	10/2013	Al-Ali	
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Examiner Signature	Date Considered
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CX-1622

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	61	8,570,503	10-2013	Hung Vo	
	62	8,577,431	11-2013	Lamego et al.	
	63	D692,145	10/2013	Al-Ali et al.	
	64	RE43,860	12/2012	Parker	
	65	2006/0076473	04/2006	Wilcken et al.	
	66	2009/0030327	01-2009	Chance, Britton	
	67	2009/0105565	04-2009	Xu	
	68	2010/0049018	02-2010	Duffy et al.	
	69	2011/0105865	05-2011	Yu et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹

17168972

Examiner Signature	/Chu Chuan Liu/	Date Considered	03/25/2014
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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Appx58897

PTO/SB/08 Equivalent

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	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze, et al.
	Art Unit	3777
	Examiner	Liu, Chu Chuan
SHEET 1 OF 3	Attorney Docket No.	CERCA.002C1

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	3	6,278,889	08-2001	Robinson	
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	5	7,509,153	03-2009	Blank et al.	
	6	7,734,320	06-2012	Al-Ali	
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	8	8,244,325	08/2012	Al-Ali et al.	
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	12	8,260,577	09/2012	Weber et al.	
	13	8,265,723	09/2012	McHale et al.	
	14	8,274,360	09/2012	Sampath et al.	
	15	8,301,217	10/2012	Al-Ali et al.	
	16	8,310,336	11/2012	Muhsin et al.	
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	19	8,346,330	01/2013	Lamego	
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	21	8,355,766	01/2013	MacNeish, III et al.	
	22	8,359,080	01/2013	Diab et al.	
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	42	8,463,349	06/2013	Diab et al.	
	43	8,466,286	06/2013	Bellot et al.	
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	63	D692,145	10/2013	Al-Ali et al.	
	64	RE43,860	12/2012	Parker	
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Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Jarom D. Kesler/Stacy Ho			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	18121393
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Jarom D. Kesler/Christina Gaul
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	CERCA.002C1
Receipt Date:	05-FEB-2014
Filing Date:	01-JUL-2010
Time Stamp:	15:23:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$180
RAM confirmation Number	1523
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

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Appx58903

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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CERCA_002C1_Response.pdf	147667 ec063af806c24640ad8e3fc0377f04d2f9c3be17	yes	9
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	9	
Warnings:					
Information:					
2		CERCA_002C1_IDS.pdf	61593 d229aba0a426d9f7e834ae9bd1a47e431da3b3e1	yes	5
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	5	
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30437 835f653ef0807d8965bf1b5f4e45ec78c95d9bd5	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			239697		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Jeroen Poeze, et al.
App. No.	:	12/829352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf. No.	:	8366

RESPONSE TO OFFICE ACTION DATED NOVEMBER 7, 2013

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated November 7, 2013, Applicant respectfully submits the following amendment and comments in connection with the above-captioned application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Application No.: 12/829352
Filing Date: July 1, 2010

AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:
 - an optical source configured to emit optical radiation onto said tissue at said measurement site;
 - at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;
 - a housing positioning said optical source and said at least one photodetector with respect to said measurement site, said housing forming a clip sensor and including:
 - a first shell housing said optical source;
 - a second shell hinged to the first shell and housing said photodetector;
 - a spring disposed between and urging together the shells;
 - a heat sink ~~operably connected to~~ integrated with and forming part of the first shell of said housing; and
 - a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site.
2. **(Original)** The sensor of claim 1, wherein said tissue at said measurement site comprises a digit of said patient.
3. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is reusable.
4. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is disposable.
5. **(Previously Presented)** The sensor of claim 1, comprising a cable connected to a patient monitor configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters.
6. **(Original)** The sensor of claim 5, wherein one of the one or more physiological parameters comprises total hemoglobin.

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7. **(Original)** The sensor of claim 5, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

8. **(Original)** The sensor of claim 1, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

9. **(Original)** The sensor of claim 1, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

10. **(Currently Amended)** A method of measuring an analyte and a temperature at a measurement site of a living patient, said method comprising:

emitting optical radiation on the measurement site from a first shell of a clip-type sensor;

detecting said optical radiation after attenuation by tissue at the measurement site in a second shell of the clip-type sensor, the first shell hinged to the second shell;

dissipating heat from the first shell using a heat sink ~~operably attached to~~ integrated with and forming part of the first shell;

measuring the temperature of said measurement site;

using a signal processor, determining an indication of perfusion from said temperature measurement; and

determining an output measurement value indicative of the analyte based on the detected streams of optical radiation.

11. **(Previously Presented)** The method of claim 10, wherein said tissue at said measurement site comprises a digit of said patient.

12. **(Previously Presented)** The method of claim 10, wherein the method further comprises correcting wavelength drift after attenuation by said tissue.

13. **(Previously Presented)** The method of claim 10, wherein said analyte comprises total hemoglobin.

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14. **(Currently Amended)** A signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the system comprising:

a noninvasive clip-type optical sensor including:

a housing including a first shell, a second shell hinged to the first shell and a spring disposed between and urging together the shells;

an optical source configured to emit optical radiation onto said tissue at said measurement site and housed in the first shell;

a heat sink integrated with and forming part of the first shell;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation, the at least one photodetector housed in the second shell;

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site;

a monitor configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters—~~and determine an indication of perfusion of the tissue at the measurement site;~~ and

a cable connected to the monitor providing communication between said optical sensor and said monitor.

15. **(Original)** The system of claim 14, wherein said tissue at said measurement site comprises a digit of said patient.

16. **(Original)** The system of claim 14, wherein at least a portion of said sensor is reusable.

17. **(Original)** The system of claim 14, wherein at least a portion of said sensor is disposable.

18. **(Original)** The system of claim 14, wherein one of the one or more physiological parameters comprises total hemoglobin.

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19. **(Original)** The system of claim 14, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

20. **(Original)** The system of claim 14, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

21. **(Original)** The system of claim 14, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

22. **(Currently Amended)** The system of claim 14, wherein said monitor comprises a handheld monitor.

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REMARKS

By way of summary, Claims 1-22 were pending in this application. In the present amendment, the Applicants have amended Claims 1, 10, 14, and 11. Accordingly, Claims 1-22 remain pending for consideration.

Objections To Claim 22

The Office Action objected to Claims 22 for minor informalities. In particular, the Office Action stated that “a” should be set forth before “handheld monitor.” In response, the Applicants have amended Claim 22 along the lines suggested in the Office Action. Accordingly, the Applicants respectfully request withdrawal of the objection to the claims.

Rejection Of Claims 1-8 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1-8 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,362,966, issued to Rosenthal, (the Rosenthal patent) in view of U.S. Pat. No. 5,851,178, issued to Aronow, (the 5,851,178 patent). The Applicants respectfully traverse this rejection for the following reasons.

Claim 1 recites, *inter alia*, “a heat sink integrated with and forming part of the first shell of said housing”. An embodiment of Claim 1 is shown, for example, in Fig. 3A, reproduced below. The heat sink 350a is integrated with and forms part of the first shell 304a.

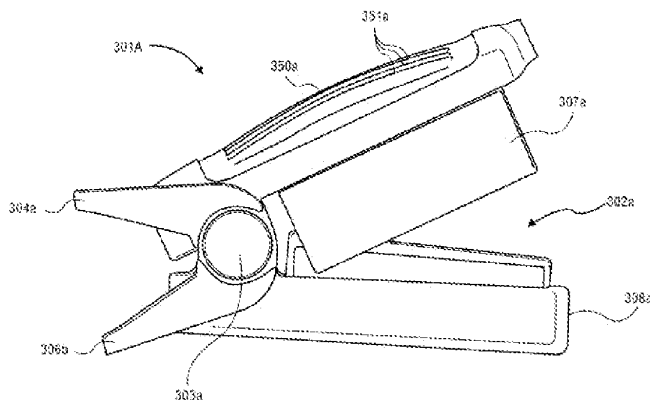
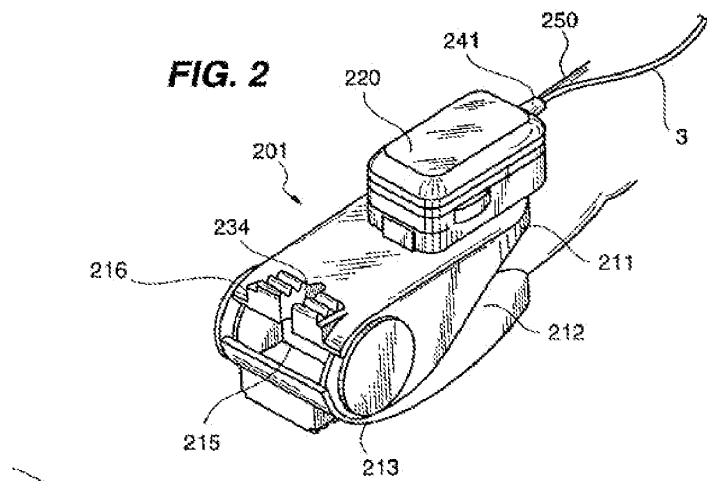


FIG. 3A

In contrast Aronow discloses a housing 220 separate from clip sensor shells 211, 212. Aronow provides no specific disclosure of what is included in housing 220 or whether it includes

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a heat sink. Rather, a heat sink is only disclosed with respect to cable connector 82, described with respect to the disposable, non-clip type sensor of Figures 4-9. Thus, Aronow does not disclose a heat sink connected a clip type sensor.



Even if Aronow was construed to imply that a connector 82 is the same as housing 220 of Fig. 2, which it should not, Aronow would still fail to disclose a heat sink integrated with and forming part of the first shell of the housing that forms part of the clip sensor. Rather, Aronow, at best, discloses that the heat sink is in a separate housing from the clip sensor housings. Thus, Aronow fails to disclose at least this limitation. Rosenthal does not disclose any type of clip sensor housing. Thus, the combination of Aronow and Rosenthal fail to disclose the limitations of Claim 1.

Claims 2-8 which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Rejection Of Claim 9 Under 35 U.S.C. § 103(a)

The Office Action rejected Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal in view of Aronow, and further in view of U.S. Pat. No. 6,606,509, issued to Schmitt (the Schmitt patent). The Applicants respectfully traverse this rejection for the following reasons. Claim 9 which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

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Rejection Of Claims 10-20 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1-8 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal, Aronow, and further in view of U.S. Pat. Pub. No. 2004/0039271. The Applicants respectfully traverse this rejection for the following reasons. Independent Claims 10 and 14 include limitations similar to that discussed above with respect to Claim 1. Specifically, that a heat sink is integrated with and forms part of a first shell of a clip type sensor. As discussed above, Aronow fails to teach or disclose such a limitation. Rosenthal and Baker are cited for other reasons and also fail to disclose at least this limitation. Thus, for the same reasons discussed above with respect to Claim 1, Applicants respectfully request the rejection of Claims 10 and 14 be withdrawn.

Claims 11-13 and 15-20 which depend from either Claims 10 or 14 are believed to be patentable for the same reasons articulated above with respect to Claims 10 and 14, and because of the additional features recited therein.

Rejection Of Claim 21 Under 35 U.S.C. § 103(a)

The Office Action rejected Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal in view of Aronow and Schmitt. The Applicants respectfully traverse this rejection for the following reasons. Claim 21 which depends from Claim 14, is believed to be patentable for the same reasons articulated above with respect to Claim 14, and because of the additional features recited therein.

Rejection Of Claim 22 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 22 under 35 U.S.C. § 103(a) as being unpatentable over Rosenthal in view of Aronow and Blank. The Applicants respectfully traverse this rejection for the following reasons. Claim 22 which depends from Claim 14, is believed to be patentable for the same reasons articulated above with respect to Claim 14, and because of the additional features recited therein.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

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application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
CERCA.002A	12/534827	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	08/03/2009
CERCA.002C1	12/829352	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	07/01/2010

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 5, 2014

By: /Jarom Kesler/
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17168711

Docket No.: CERCA.002C1

Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

Inventor	:	Marcelo Lamego
App. No.	:	12/829352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf. No.	:	8366

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a First Office Action, but before the mailing date of a Final Action and before the mailing date of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. 1.17(p).

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Filing Date: July 1, 2010

The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 5, 2014

By: /Jarom Kesler/
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17169696

CX-1622

PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		<input type="checkbox"/> To be Mailed	
Substitute for Form PTO-875				12/829,352		07/01/2010			
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL					
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	02/05/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE		0			
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
				TOTAL ADD'L FEE					
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	11/07/2013
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
11/07/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Office Action Summary	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 09/18/2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5) ☒ Claim(s) 1-22 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-22 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some * c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04/17/2013.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.

4) ☐ Other: ____.

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DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/26/2013 has been entered.
3. Claims 1-22 are pending for examination.

Claim Objections

4. Claim 22 is objected to because of the following informalities: In regard to claim 22, "a" should be set forth before "handheld monitor". Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (USPN 5,362,966 - cited in previous action) in view of Aronow (USPN 5,851,178). In regard to claim 1, Rosenthal discloses a noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Col 1 line 1 - Col 2 line 41 and Fig. 1), the sensor comprising: an optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15) configured to emit optical radiation onto said tissue at said measurement site (Fig. 1); at least one photodetector (element 8, Fig. 1) configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (Fig. 1) and output at least one respective signal stream responsive to said detected optical radiation (through connection between element 8 and processor 10, Fig. 1); a housing positioning said optical source and said at least one photodetector with respect to said measurement site (element 28 in element 1, Fig. 1); a thermistor (element 29, Fig. 1) operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 and Col 2 lines 25-41). Rosenthal does not specifically said housing forming a clip sensor and including: a first shell housing said optical source; a second shell hinged to the first shell and housing said photodetector; a spring disposed between and urging together the shells; and a heat sink operably connected to the first shell of said housing. Aronow teaches a housing forming a clip sensor (Figs. 1-4) and including: a first shell (element 211 and 220, Figs. 2-3) housing an optical source (elements 416, Fig. 4); a second shell (element 212, Fig. 3) hinged to the first shell (Fig. 3) and housing said photodetector (element 333, Fig. 3); a spring

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disposed between and urging together the shells (element 314, Fig. 3); and a heat sink operably connected to the first shell of said housing (heat sinks 414 and 415, Fig. 4). It is known that a separate sensor structure is considered as much easier for performing regular maintenances such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a separate clip sensor (Aronow) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts.

In regard to claim 2, Rosenthal as modified by Aronow discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and Fig. 2 of Aronow).

In regard to claim 3, Rosenthal as modified by Aronow discloses at least a portion of said housing is reusable (element 1, Fig. 1 Rosenthal; Figs. 2-4 of Aronow).

In regard to claim 4, Rosenthal as modified by Aronow discloses at least a portion of said housing is disposable (element 20, Fig. 1 Rosenthal; elements 321, Fig. 3 of Aronow).

In regard to claim 5, Rosenthal as modified by Aronow discloses a cable connected to a patient monitor (Fig. 1 of Aronow) configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal).

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In regard to claim 6, Rosenthal as modified by Aronow discloses one of the one or more physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow).

In regard to claim 7, Rosenthal as modified by Aronow discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 8, Rosenthal as modified by Aronow discloses the sensor comprises a photodetector (element 28 in element 1, Fig. 1 of Rosenthal) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal). Rosenthal as modified by Aronow does not specifically disclose a plurality of photodetectors. However, wavelength-specific photodetectors are well known in the art. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to substitute photodetector with wavelength-specific photodetectors to yield predictable results.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal and Aronow as applied to claim 5 above, and further in view of Schmitt (USPN 6,606,509 – cited in previous action). In regard to claim 9, Rosenthal as modified by Aronow discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and

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about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Aronow) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/hydration information.

8. Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal in view of Aronow and further in view Blank et al. (USPGPUB 2004/0039271). In regard to claim 10, Rosenthal discloses a method of measuring an analyte and a temperature at a measurement site of a living patient (Fig. 1), said method comprising: emitting optical radiation on the measurement site (elements 5 and 6, Fig. 1); detecting said optical radiation after attenuation by tissue at the measurement site (element 8, Fig. 1); measuring the temperature of said measurement site (element 29, Fig. 1); using a signal processor (element 10, Fig. 1), determining an output measurement value indicative of the analyte based on the detected streams of optical radiation (glucose concentration, Col 1 lines 26-63). Rosenthal does not specifically disclose a sensor configuration of a clip sensor. Aronow teaches a housing forming a clip sensor (Figs. 1-4) and including: a first shell (element 211 and 220, Figs. 2-3) housing an optical source (elements 416, Fig. 4); a second shell (element 212, Fig. 3) hinged to the first shell (Fig. 3) and housing said photodetector (element 333, Fig. 3); a

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spring disposed between and urging together the shells (element 314, Fig. 3); and a heat sink operably connected to the first shell of said housing (heat sinks 414 and 415, Fig. 4). It is known that a separate sensor structure is considered as much easier for performing regular maintenances such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a separate clip sensor (Aronow) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts. Rosenthal as modified by Aronow does not specifically disclose determining an indication of perfusion from said temperature measurement. Blank teaches localized perfusion is important because the surface capillaries affect the amount of blood present near the skin surface ([0036]). The change can affect the optical measurement for detecting a blood analyte concentration ([0036]) and skin temperature affects perfusion ([0041]). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the method (Rosenthal as modified by Aronow) to determine an indication of perfusion through the measurements of skin temperatures (Blank) in order to facilitate the optical detection of analyte.

In regard to claim 11, Rosenthal as modified by Aronow and Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal).

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In regard to claim 12, Rosenthal as modified by Aronow and Blank discloses correcting wavelength drift after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 13, Rosenthal as modified by Aronow and Blank discloses said analyte comprises total hemoglobin (Col 2 lines 11-23 of Aronow)

In regard to claim 14, Rosenthal as modified by Aronow and Blank discloses a signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Fig. 1 of Rosenthal), the system comprising: a noninvasive optical clip type sensor (section 2, Fig. 1 of Rosenthal; Figs. 2-4 of Aronow) including: a housing forming a clip sensor (Figs. 1-4 of Aronow) and including: a first shell (element 211 and 220, Figs. 2-3) housing an optical source (elements 416, Fig. 4 of Aronow); a second shell (element 212, Fig. 3 of Aronow) hinged to the first shell (Fig. 3 of Aronow) and housing said photodetector (element 333, Fig. 3 of Aronow); a spring disposed between and urging together the shells (element 314, Fig. 3 of Aronow); an optical source configured to emit optical radiation onto said tissue at said measurement site (elements 5 and 6, Fig. 1 of Rosenthal; Figs. 2-4 of Aronow); at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (element 8, Fig. 1 of Rosenthal) and output at least one respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal); a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 of Rosenthal); a monitor (element 10, Fig. 1

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of Rosenthal and element 2, Figs. Fig. 1 of Aronow) configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal); and determine an indication of perfusion of the tissue at the measurement site (referring to claim 10 above); and a cable connected to the monitor providing communication between said optical sensor and said monitor (Fig. 1 of Aronow).

In regard to claim 15, Rosenthal as modified by Aronow and Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and Fig. 2 of Aronow).

In regard to claim 16, Rosenthal as modified by Aronow and Blank discloses at least a portion of said sensor is reusable (element 1, Fig. 1 Rosenthal; Figs. 2-4 of Aronow).

In regard to claim 17, Rosenthal as modified by Aronow and Blank discloses at least a portion of said sensor is disposable (element 20, Fig. 1 Rosenthal; elements 321, Fig. 3 of Aronow).

In regard to claim 18, Rosenthal as modified by Aronow and Blank discloses one of the one or more physiological parameters comprises total hemoglobin (Col 2 lines 11-23 of Aronow).

In regard to claim 19, Rosenthal as modified by Aronow and Blank discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 line 1 - Col 2 line 41 of Rosenthal).

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In regard to claim 20, Rosenthal as modified by Aronow and Blank discloses the sensor comprises a photodetector (element 28 in element 1, Fig. 1 of Rosenthal) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal). Rosenthal as modified by Aronow and Blank does not specifically disclose a plurality of photodetectors. However, wavelength-specific photodetectors are well known in the art. It would have been obvious to one with ordinary skill in the art at the time of the invention was made to substitute photodetector with wavelength-specific photodetectors to yield predictable results.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Aronow and Blank as applied to claim 14 above, and further in view of Schmitt. In regard to claim 21, Rosenthal as modified by Aronow and Blank discloses all the claimed limitations except the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm. Schmitt teaches the optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt). It would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Aronow and Blank) to incorporate more NIR wavelengths (Schmitt) in order to obtain

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more physiological parameters of the tissue such as HBT, HCT or water fraction/hydration information.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Aronow and Blank as applied to claim 14 above, and further in view of Al-Ali et al. (USPGPUB 2006/0220881). In regard to claim 22, Rosenthal as modified by Aronow and Blank discloses all the claimed limitations except said monitor comprises handheld monitor. Al-Ali teaches a handheld monitor (abstract; Figs. 2, 7 and 11A) configured to be connected to a clip style sensor ([0040]) for displaying physiological parameters. Rosenthal as modified by Aronow and Blank discloses a monitor (Fig. 1 of Aronow). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the system (Rosenthal as modified by Aronow and Blank) to incorporate a handheld monitor (Al-Ali) in order to increase the portability of the system.

Response to Arguments

11. Applicant's amendment and remarks with respect to claims 1-22 have been fully considered but they are deemed to be moot in views of the new grounds of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 7:00am~3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777

/Chu Chuan Liu/
Examiner, Art Unit 3777

Notice of References Cited	Application/Control No. 12/829,352	Applicant(s)/Patent Under Reexamination POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2006/0220881	10-2006	Al-Ali et al.	600/310
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.


EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S62	108	shell and spring and finger and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:47
S61	113	("6213952").URPN.	USPAT	OR	ON	2013/10/28 14:31
S60	426	pressure with finger and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:18
S59	30	upper with shell and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:16
S58	3	active with pulse and shell and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:14
S57	5	inflatable and shell and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:13
S56	312	shell and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:11
S55	13	handheld and clip and shell and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:10
S54	7964	handheld and clip and shell 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 14:09
S53	98	handheld and clip and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/10/28 13:54
S52	1	("6353750").PN.	US-PGPUB; USPAT	OR	OFF	2013/10/28 12:39

EAST Search History (Interference)

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10/ 29/ 2013 9:56:04 AM**C:\ Users\ cliu\ Documents\ EAST\ Workspaces\ 12829352.wsp**

<i>Index of Claims</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant		<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47			
CLAIM		DATE							
Final	Original	11/01/2012	04/10/2013	10/29/2013					
	1	✓	✓	✓					
	2	✓	✓	✓					
	3	✓	✓	✓					
	4	✓	✓	✓					
	5	✓	✓	✓					
	6	✓	✓	✓					
	7	✓	✓	✓					
	8	✓	✓	✓					
	9	✓	✓	✓					
	10	✓	✓	✓					
	11	✓	✓	✓					
	12	✓	✓	✓					
	13	✓	✓	✓					
	14	✓	✓	✓					
	15	✓	✓	✓					
	16	✓	✓	✓					
	17	✓	✓	✓					
	18	✓	✓	✓					
	19	✓	✓	✓					
	20	✓	✓	✓					
	21	✓	✓	✓					
	22	✓	✓	✓					

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
SHEET 1 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	5,441,054	08-1995	Tsuchiya	
	2	5,452,717	09-1995	Branigan et al.	
	3	6,636,759	10-2003	Robinson	
	4	2004/0039272	02-2004	Abdul-Hafiz et al.	
	5	2005/0162761	07-2005	Hargis et al.	
	6	2006/0167347	07-2006	Xu et al.	
	7	2006/0189859	08-2006	Kiani et al.	
	8	D551,350	09-2007	Lorimer et al.	
	9	D553,248	10-2007	Nguyen	
	10	D562,985	02-2008	Brefka et al.	
	11	D567,125	04-2008	Okabe et al.	
	12	D569,001	05-2008	Omaki	
	13	D569,521	05-2008	Omaki	
	14	2009/0105565	04-2009	Xu	
	15	7,606,606	10-2009	Laakkonen	
	16	2010/0049018	02-2010	Duffy et al.	
	17	6,278,889	08-2013	Robinson	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	18	PCT International Search Report, App. No. PCT/US2010/047899, Date of Actual Completion of Search: 01/26/2011, 4 pages.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when English language translation is attached.

CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu,Chu Chuan
SHEET 2 OF 2	Attorney Docket No.	CERCA.002C1


NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	19	International Preliminary Report on Patentability and Written Opinion of the International Searching Authority issued in Application No. PCT US2009/049638, mailed January 5, 2011 in 9 pages.	
	20	European Office Action issued in application no. 10763901.5 on 01/11/2013.	

15229985

Examiner Signature	/Chu Chuan Liu/	Date Considered	10/29/2013
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

T¹ - Place a check mark in this area when an English language translation is attached.

Appx58935

Search Notes 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	04/10/2013	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	10/29/2013	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	04/10/2013	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	10/29/2013	CCL

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/CHU CHUAN (JJ) LIU/ Examiner.Art Unit 3777	
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Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

CX-1622
PTO/SB/30EFS (07-09)Approved for use through 07/31/2012. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)**

Application Number	12829352	Filing Date	2010-07-01	Docket Number (if applicable)	CERCA.002C1	Art Unit	3777
First Named Inventor	Jeroen Poeze			Examiner Name	Liu, Chu Chuan		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.☒ Consider the arguments in the Appeal Brief or Reply Brief previously filed on 2013-08-26☐ Other _____☐ Enclosed☐ Amendment/Reply☐ Information Disclosure Statement (IDS)☐ Affidavit(s)/ Declaration(s)☐ Other _____**MISCELLANEOUS**☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)☐ Other _____**FEES****The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
Deposit Account No 111410**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**☒ Patent Practitioner Signature☐ Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

CX-1622
PTO/SB/30EFS (07-09)

Approved for use through 07/31/2012. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Jarom Kesler/	Date (YYYY-MM-DD)	2013-09-18
Name	Jarom Kesler	Registration Number	57046

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Jarom D. Kesler/Stacy Ho			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	1251	1	200	200

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
Total in USD (\$)				1400

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	16886021
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Jarom D. Kesler/Kevin Kraus
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	CERCA.002C1
Receipt Date:	18-SEP-2013
Filing Date:	01-JUL-2010
Time Stamp:	14:12:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1400
RAM confirmation Number	556
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

Page 664 of 1082

Appx58942

CX-1622

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	CERCA_002C1_RCE.pdf	697850	no	3
			b29fbdef056f301c2a2d82d3846ed255953d52a		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32295	no	2
			a50932051c6abd829994d6a9431280298f17765		
Warnings:					
Information:					
Total Files Size (in bytes):			730145		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

CX-1622



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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 Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	09/12/2013
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
09/12/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Advisory Action Before the Filing of an Appeal Brief	Application No. 12/829,352	Applicant(s) POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	AIA (First Inventor to File) Status No

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 August 2013 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.
NO NOTICE OF APPEAL FILED

1. ☒ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires _____ months from the mailing date of the prior Advisory Action or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.

Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because

a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

b) ☐ They raise the issue of new matter (see NOTE below);

c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): (a) ☐ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

13. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 04/17/2013

14. ☐ Other: _____.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-22.

Claim(s) withdrawn from consideration: _____.

/Tse Chen/ Supervisory Patent Examiner, Art Unit 3777	/Chu Chuan Liu/ Examiner, Art Unit 3777
--	--

Continuation Sheet (PTOL-303)

Application No. 12/829,352 CX-1622

Continuation of 3. NOTE: The amendments contain additional elements/ configurations and require further consideration and/ or search .

DO NOT ENTER: /CCL/

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Jeroen Poeze, et al.
App. No.	:	12/829,352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf No.	:	8366

RESPONSE TO FINAL OFFICE ACTION DATED APRIL 24, 2013

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Final Office Action dated April 24, 2013, Applicant respectfully submits the following amendment and comments in connection with the above-captioned application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	: Jeroen Poeze, et al.
App. No.	: 12/829,352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf No.	: 8366

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Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Application No.: 12/829,352
Filing Date: July 1, 2010

AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:
 - an optical source configured to emit optical radiation onto said tissue at said measurement site;
 - at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;
 - a housing positioning said optical source and said at least one photodetector with respect to said measurement site, said housing forming a clip sensor and including:
 - a first shell housing said optical source;
 - a second shell hinged to the first shell and housing said photodetector;
 - a spring disposed between and urging together the shells;
 - a heat sink operably connected to the first shell of said housing; and
 - a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site.
2. **(Original)** The sensor of claim 1, wherein said tissue at said measurement site comprises a digit of said patient.
3. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is reusable.
4. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is disposable.
5. **(Previously Presented)** The sensor of claim 1, comprising a cable connected to a patient monitor configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters.
6. **(Original)** The sensor of claim 5, wherein one of the one or more physiological parameters comprises total hemoglobin.
7. **(Original)** The sensor of claim 5, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

Application No.: 12/829,352
Filing Date: July 1, 2010

8. **(Original)** The sensor of claim 1, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

9. **(Original)** The sensor of claim 1, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

10. **(Currently Amended)** A method of measuring an analyte and a temperature at a measurement site of a living patient, said method comprising:

emitting optical radiation on the measurement site from a first shell of a clip-type sensor;

detecting said optical radiation after attenuation by tissue at the measurement site in a second shell of the clip-type sensor, the first shell hinged to the second shell;

dissipating heat from the first shell using a heat sink operably attached to the first shell;

measuring the temperature of said measurement site;

using a signal processor, determining an indication of perfusion from said temperature measurement; and

determining an output measurement value indicative of the analyte based on the detected streams of optical radiation.

11. **(Previously Presented)** The method of claim 10, wherein said tissue at said measurement site comprises a digit of said patient.

12. **(Previously Presented)** The method of claim 10, wherein the method further comprises correcting wavelength drift after attenuation by said tissue.

13. **(Previously Presented)** The method of claim 10, wherein said analyte comprises total hemoglobin.

Application No.: 12/829,352
Filing Date: July 1, 2010

14. **(Currently Amended)** A signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the system comprising:

a noninvasive clip-type optical sensor including:

a housing including a first shell, a second shell hinged to the first shell and a spring disposed between and urging together the shells

an optical source configured to emit optical radiation onto said tissue at said measurement site and housed in the first shell;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation, the at least one photodetector housed in the second shell;

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site;

a monitor configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters and determine an indication of perfusion of the tissue at the measurement site; and

a cable connected to the monitor providing communication between said optical sensor and said monitor.

15. **(Original)** The system of claim 14, wherein said tissue at said measurement site comprises a digit of said patient.

16. **(Original)** The system of claim 14, wherein at least a portion of said sensor is reusable.

17. **(Original)** The system of claim 14, wherein at least a portion of said sensor is disposable.

18. **(Original)** The system of claim 14, wherein one of the one or more physiological parameters comprises total hemoglobin.

Application No.: 12/829,352
Filing Date: July 1, 2010

19. **(Original)** The system of claim 14, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

20. **(Original)** The system of claim 14, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

21. **(Original)** The system of claim 14, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

22. **(Original)** The system of claim 14, wherein said monitor comprises handheld monitor.

Application No.: 12/829,352
Filing Date: July 1, 2010

REMARKS

The Applicants thank the Examiner for the examination of the present application. By way of summary, Claims 1-22 were pending in this application. In the present amendment, the Applicants have amended Claims 1, 10 and 14. Accordingly, Claims 1-22 remain pending for consideration.

Rejection Of Claims 1-4 Under 35 U.S.C. § 103

The Office Action rejected Claims 1-4 under 35 U.S.C. § 103 as being unpatentable over U.S. patent no. 5,362,966, issued to Rosenthal et al., (the Rosenthal patent) in view of U.S. patent no. 5,131,391, issued to Sakai et al., (the Sakai patent). The Applicants respectfully traverse this rejection for the following reasons. The Rosenthal patent, alone or in combination with the Sakai patent fail to teach or disclose the claimed sensor housing configuration in combination with the heat sink and thermistor of Claims 1-4. For example, one embodiment of the claimed housing configuration (discussed by way of example and not limitation) is illustrated in Fig. 3A of the present Application. Because neither Rosenthal nor Sakai teach such a system, Applicant's respectfully request that this rejection be withdrawn.

Rejection Of Claims 5 and 7-8 Under 35 U.S.C. § 103

The Office Action rejected Claims 5 and 7-8 under 35 U.S.C. § 103 as being unpatentable over Rosenthal in view of Sakai and further in view of U.S. patent No. 6,353,750 issued to Kimura et al., (the Kimura patent). Claims 5 and 7-8, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1 and because of the additional limitations recited therein.

Rejection Of Claims 10-12 Under 35 U.S.C. § 103

The Office Action rejected Claims 10-12 under 35 U.S.C. § 103 as being unpatentable over Rosenthal in view of U.S. pat. pub. No. 2004/0039271 by Blank et al., (the Blank publication). The Applicants respectfully traverse this rejection for the following reasons. The Rosenthal patent, alone or in combination with the Blank publication fail to teach or disclose the claimed sensor housing configuration in combination with the other elements of Claims 10-12. Because neither Rosenthal nor Blank teach such a system, Applicant's respectfully request that this rejection be withdrawn.

Application No.: 12/829,352
Filing Date: July 1, 2010

Rejection Of Claims 14-17, 19-20 and 22 Under 35 U.S.C. § 103

The Office Action rejected Claims 14-17, 19-20 and 22 under 35 U.S.C. § 103 as being unpatentable over Rosenthal in view Blank and further in view of Kimura. The Rosenthal patent, alone or in combination with the Blank publication and the Kimura patent fail to teach or disclose the claimed sensor housing configuration in combination with the other elements of Claims 14-17, 19-20 and 22. Because neither the Rosenthal, Blank, nor Kimura patents teach such a system, Applicant's respectfully request that this rejection be withdrawn.

Rejection Of Claims 6 and 9 Under 35 U.S.C. § 103

The Office Action rejected Claims 6 and 9 under 35 U.S.C. § 103 as being unpatentable over Rosenthal in view of Sakai and Kimura and further in view of U.S. patent No. 6,606,509 issued to Schmitt et al., (the Schmitt patent). Claims 6 and 9, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1 and because of the additional limitations recited therein.

Rejection Of Claim 13 Under 35 U.S.C. § 103

The Office Action rejected Claim 13 under 35 U.S.C. § 103 as being unpatentable over Rosenthal in view of Blank and further in view of Schmitt. Claim 13, which depends from Claim 10, is believed to be patentable for the same reasons articulated above with respect to Claim 10 and because of the additional limitations recited therein.

Rejection Of Claims 18 and 21 Under 35 U.S.C. § 103

The Office Action rejected Claim 18 and 21 under 35 U.S.C. § 103 as being unpatentable over Rosenthal and Blank and Kimura. Claims 18 and 21, which depend from Claim 14, are believed to be patentable for the same reasons articulated above with respect to Claim 14 and because of the additional limitations recited therein.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other

Application No.: 12/829,352
Filing Date: July 1, 2010

broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
CERCA.002A	12/534,827	Multi-Stream Data Collection System for Noninvasive Measurement of Blood Constituents	8/3/2009
CERCA.011A	12/497,506	Heat Sink for Noninvasive Medical Sensor	7/2/2009

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 26, 2013

By: /Jarom Kesler/
Jarom D. Kesler
Registration No. 57,046
Attorney of Record
Customer No. 20995
(949) 760-0404

15350001

Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Jarom D. Kesler/Stacy Ho			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	1251	1	200	200

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				200

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	16689891
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Jarom D. Kesler/Heide Young
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	CERCA.002C1
Receipt Date:	26-AUG-2013
Filing Date:	01-JUL-2010
Time Stamp:	19:13:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$200
RAM confirmation Number	7041
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

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Appx58958

CX-1622

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CERCA_002C1_Response.pdf	40979 0ff5dd0cde50446b011f5ef434259140beb08ed4	yes	8
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Response After Final Action		1	1	
	Claims		2	5	
	Applicant Arguments/Remarks Made in an Amendment		6	8	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30538 6f20d26c201dfb728a15d54a6aae209e5e39339	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			71517		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

CX-1622

PTO/SB/06 (09-11)

Approved for use through 1/31/2014. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD				Application or Docket Number		Filing Date		<input type="checkbox"/> To be Mailed	
Substitute for Form PTO-875				12/829,352		07/01/2010			
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL					
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	08/26/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$80 =		0	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE						0			
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
TOTAL ADD'L FEE									
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CX-1622



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	04/24/2013
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
04/24/2013	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

CX-1622

Office Action Summary	Application No. 12/829,352		Applicant(s) KIANI ET AL.	
	Examiner CHU CHUAN (JJ) LIU		Art Unit 3777	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 21 February 2013.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5) ☒ Claim(s) 1-22 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-22 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some * c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Interim copies:

a) ☐ All b) ☐ Some c) ☐ None of the: Interim copies of the priority documents have been received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/20/2013.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.

4) ☐ Other: ____.

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DETAILED ACTION

1. Applicant's amendments/ remarks filed on 02/21/2013 have been fully considered.
2. Claims 1-22 are pending for examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (USPN 5,362,966 - cited in previous action) in view of Sakai et al. (USPN 5,131,391 – applicant cited). In regard to claim 1, Rosenthal discloses a noninvasive sensor configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Col 1 line 1 - Col 2 line 41 and Fig. 1), the sensor comprising: an optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15) configured to emit optical radiation onto said tissue at said measurement site (Fig. 1); at least one photodetector (element 8, Fig. 1) configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (Fig. 1) and output at least one respective signal stream responsive to said detected optical radiation (through connection between element 8 and processor 10, Fig. 1); a housing

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positioning said optical source and said at least one photodetector with respect to said measurement site (element 28 in element 1, Fig. 1); a thermistor (element 29, Fig. 1) operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 and Col 2 lines 25-41). Rosenthal does not specifically a heat sink operably connected to said housing. Sakai teaches a heat sink operably connected to a housing of an optical sensor (element 72, Fig. 5). It is well known that LEDs generate heat when emitting light. The heat generated by the IREDs 5 may influence the reading of the temperature sensor and the temperature of the measuring site (Fig. 1 of Rosenthal). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a heat sink to the housing (Sakai) in order to reduce the influence of the heat generated by the IREDs to prevent inaccurate measurements.

In regard to claim 2, Rosenthal as modified by Sakai discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal).

In regard to claim 3, Rosenthal as modified by Sakai discloses at least a portion of said housing is reusable (element 1, Fig. 1 Rosenthal).

In regard to claim 4, Rosenthal as modified by Sakai discloses at least a portion of said housing is disposable (element 20, Fig. 1 Rosenthal).

5. Claims 5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal and Sakai as applied to claim 1 above, and further in

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view of Kimura et al. (USPN 6,353,750 – cited in previous action). In regard to claim 5, Rosenthal as modified by Sakai discloses a patient monitor (element 10, Fig. 1 of Rosenthal) configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal). Rosenthal as modified by Sakai does not specifically disclose the sensor comprises a cable connected to a patient monitor. Kimura teaches an optical sensor comprises a cable connected to a patient monitor for non-invasive blood constituent analysis (Figs. 1 and 2). It is known that a separate sensor structure is considered as much easier for performing regular maintenance such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Sakai) to incorporate a separate sensor and a cable (Kimura) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts.

In regard to claim 7, Rosenthal as modified by Sakai and Kimura discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 8, Rosenthal as modified by Sakai and Kimura discloses the sensor comprises plurality of photodetectors (element 12, Fig. 1 and Col 5 lines 15-21 of Kimura) configured to detect the optical radiation from said optical source (elements 5

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and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal).

6. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal in view of Blank et al. (USPGPUB 2004/0039271). In regard to claim 10, Rosenthal discloses a method of measuring an analyte and a temperature at a measurement site of a living patient (Fig. 1), said method comprising: emitting optical radiation on the measurement site (elements 5 and 6, Fig. 1); detecting said optical radiation after attenuation by tissue at the measurement site (element 8, Fig. 1); measuring the temperature of said measurement site (element 29, Fig. 1); using a signal processor (element 10, Fig. 1), determining an output measurement value indicative of the analyte based on the detected streams of optical radiation (glucose concentration, Col 1 lines 26-63). Rosenthal does not specifically disclose determining an indication of perfusion from said temperature measurement. Blank teaches localized perfusion is important because the surface capillaries affect the amount of blood present near the skin surface ([0036]). The change can affect the optical measurement for detecting a blood analyte concentration ([0036]) and skin temperature affects perfusion ([0041]). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the method to determine an indication of perfusion through the measurements of skin temperatures in order to facilitate the optical detection of analyte.

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In regard to claim 11, Rosenthal as modified by Blank discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal).

In regard to claim 12, Rosenthal as modified by Blank discloses correcting wavelength drift after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

7. Claims 14-17, 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal and Blank as applied to claim 10 above, and further in view of Kimura. In regard to claim 14, Rosenthal as modified by Blank discloses a signal processing system configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient (Fig. 1 of Rosenthal), the system comprising: a noninvasive optical sensor (section 2, Fig. 1 of Rosenthal) including: an optical source configured to emit optical radiation onto said tissue at said measurement site (elements 5 and 6, Fig. 1 of Rosenthal); at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (element 8, Fig. 1 of Rosenthal) and output at least one respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal); a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 of Rosenthal); a monitor (element 10, Fig. 1 of Rosenthal and element 2, Figs. 1 and 2 of Kimura) configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal); and determine an indication of perfusion of the tissue at the measurement site (referring to claim 10 above). Rosenthal as modified

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by Blank does not specifically disclose a cable connected to the monitor providing communication between said optical sensor and said monitor. Kimura teaches an optical sensor comprises a cable connected to a patient monitor for non-invasive blood constituent analysis (Figs. 1 and 2). It is known that a separate sensor structure is considered as much easier for performing regular maintenance such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Blank) to incorporate a separate sensor and a cable (Kimura) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts.

In regard to claim 15, Rosenthal as modified by Blank and Kimura discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and Fig. 2 of Kimura).

In regard to claim 16, Rosenthal as modified by Blank and Kimura discloses at least a portion of said sensor is reusable (element 1, Fig. 2 of Kimura).

In regard to claim 17, Rosenthal as modified by Blank and Kimura discloses at least a portion of said sensor is disposable (element 1, Fig. 2 of Kimura).

In regard to claim 19, Rosenthal as modified by Blank and Kimura discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 line 1 - Col 2 line 41 of Rosenthal).

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In regard to claim 20, Rosenthal as modified by Blank and Kimura discloses the sensor comprises plurality of photodetectors (element 12, Fig. 1 and Col 5 lines 15-21 of Kimura) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal).

In regard to claim 22, Rosenthal as modified by Blank and Kimura discloses said monitor comprises handheld monitor (hand-held unit 1, Fig. 1 of Rosenthal).

8. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Sakai and Kimura as applied to claims 5 above, and further in view of Schmitt (USPN 6,606,509 – cited in previous action). In regard to claim 6, Rosenthal as modified by Sakai and Kimura discloses all the claimed limitations except the one or more physiological parameters comprise total hemoglobin. Schmitt teaches NIR wavelengths can be used to determine total hemoglobin concentration, hematocrit and water fraction of the finger (abstract; Col 7 lines 7-20; Fig. 6). Rosenthal as modified by Sakai and Kimura discloses six or more IREDs can be utilized to measure a blood analyte from a finger (Col 1 line 64 – Col 2 line 13 and Fig. 1 of Rosenthal). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal as modified by Sakai and Kimura) to incorporate more NIR wavelengths (Schmitt) in order to obtain

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more physiological parameters of the tissue such as HBT, HCT or water fraction/hydration information.

In regard to claim 9, Rosenthal as modified by Sakai, Kimura and Schmitt discloses optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt).

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal and Blank as applied to claims 10 above, and further in view of Schmitt. In regard to claim 13, Rosenthal as modified by Blank discloses all the claimed limitations except the one or more physiological parameters comprise total hemoglobin. Schmitt teaches NIR wavelengths can be used to determine total hemoglobin concentration, hematocrit and water fraction of the finger (abstract; Col 7 lines 7-20; Fig. 6). Rosenthal as modified by Kimura discloses six or more IREDs can be utilized to measure a blood analyte from a finger (Col 1 line 64 – Col 2 line 13 and Fig. 1 of Rosenthal). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the method (Rosenthal as modified by Blank) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/hydration information.

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10. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal, Blank and Kimura as applied to claims 14 above, and further in view of Schmitt. In regard to claim 18, Rosenthal as modified by Blank and Kimura discloses all the claimed limitations except the one or more physiological parameters comprises total hemoglobin. Schmitt teaches NIR wavelengths can be used to determine total hemoglobin concentration, hematocrit and water fraction of the finger (abstract; Col 7 lines 7-20; Fig. 6). Rosenthal as modified by Blank and Kimura discloses six or more IREDs can be utilized to measure a blood analyte from a finger (Col 1 line 64 – Col 2 line 13 and Fig. 1 of Rosenthal). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the system (Rosenthal as modified by Blank and Kimura) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/ hydration information.

In regard to claim 21, Rosenthal as modified by Blank, Kimura and Schmitt discloses optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt).

Response to Arguments

11. Applicant's arguments, see page 5 of Remarks, filed on 02/21/2013, with respect to claims 10-14 and claims 1, 5, and 14 have been fully considered and are persuasive.

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The objection of claims 10-14 and the 35 USC 112 rejection of claims 1, 5 and 14 have been withdrawn.

12. Applicant's amendment and argument with respect to claims 1-22 filed on 02/21/2013 have been fully considered but they are deemed to be moot in views of the new grounds of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 7:00am~3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chu Chuan Liu/
Examiner, Art Unit 3777

/Eric Winakur/
Primary Examiner, Art Unit 3777

Notice of References Cited	Application/Control No. 12/829,352	Applicant(s)/Patent Under Reexamination KIANI ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2004/0039271	02-2004	Blank et al.	600/322
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant				<input type="checkbox"/> CPA		<input type="checkbox"/> T.D.		<input type="checkbox"/> R.1.47	
CLAIM		DATE							
Final	Original	11/01/2012	04/10/2013						
	1	✓	✓						
	2	✓	✓						
	3	✓	✓						
	4	✓	✓						
	5	✓	✓						
	6	✓	✓						
	7	✓	✓						
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	11	✓	✓						
	12	✓	✓						
	13	✓	✓						
	14	✓	✓						
	15	✓	✓						
	16	✓	✓						
	17	✓	✓						
	18	✓	✓						
	19	✓	✓						
	20	✓	✓						
	21	✓	✓						
	22	✓	✓						


EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S51	88	perfusion with temperature and thermistor and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/10 14:21
S50	11	perfusion with temperature and thermistor and total adj hemoglobin and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/09 09:14
S49	26	perfusion with temperature and total adj hemoglobin and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/09 09:11
S48	163	perfusion with temperature and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/09 09:04
S47	1	S46 and NIR	US-PGPUB; USPAT	OR	ON	2013/04/09 09:02
S46	42	S45 and glucose	US-PGPUB; USPAT	OR	ON	2013/04/09 08:56
S45	89	perfusion adj index and temperature and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/09 08:55
S44	637	perfusion and temperature and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/09 08:54
S43	1	("5131391").PN.	US-PGPUB; USPAT	OR	OFF	2013/04/09 08:51
S42	1	("5159929").PN.	US-PGPUB; USPAT	OR	OFF	2013/04/09 08:49
S41	16	heat adj sink.clm. and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2013/04/09 08:44

EAST Search History (Interference)

< This search history is empty >

4/ 10/ 2013 3:29:03 PM**C:\Users\cliu\Documents\EAST\Workspaces\12829352.wsp**

Search Notes 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	04/10/2013	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL
Updated EAST Search (TEXT, USPGPUB, USPAT) See Search History	04/10/2013	CCL

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/CHU CHUAN (JJ) LIU/ Examiner.Art Unit 3777	
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CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
SHEET 1 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	2002/0016536	02-2002	Benni, Paul	
	2	2002/0039272	04-2002	Abdul-Hafiz et al.	
	3	2002/0052547	05-2002	Toida, Masahiro	
	4	2002/0091322	07-2002	Chaiken et al.	
	5	2002/0115918	08-2002	Crowley, Robert J.	
	6	2004/0054269	03-2004	Rantala et al.	
	7	2006/0167347	07-2006	Xu et al.	
	8	2006/0189859	08-2006	Kiani et al.	
	9	2006/0208191	09-2006	Kessler et al.	
	10	2006/0258922	11-2006	Mason et al.	
	11	2007/0149865	06-2007	Laakkonen	
	12	2007/0165218	07-2007	Qing et al.	
	13	2007/0197886	08-2007	Naganuma et al.	
	14	2007/0293792	12-2007	Sliwa et al.	
	15	2008/0036855	02-2008	Heenan, Adam John	
	16	2008/0036855	02-2008	Heenan, Adam John	
	17	2008/0071154	03-2008	Hausmann et al.	
	18	2008/0130232	06-2008	Yamamoto et al.	
	19	2008/0139908	06-2008	Kurth, charles dean	
	20	2008/0208006	08-2008	Farr, Mina	
	21	2009/0043180	02-2009	Tschautscher et al.	
	22	2009/0163775	06-2009	Barrett et al.	
	23	2010/0004518	01-2010	Vo et al.	
	24	2010/0049018	02-2010	Duffy et al.	
	25	2010/0090118	04-2010	Rozenfeld, Anatoly	
	26	4,114,604	09-1978	Shaw et al.	
	27	4,444,471	04-1984	Ford et al.	
	28	4,655,225	04-1987	Dahne et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when each U.S. Patent is attached. **ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/**

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
SHEET 2 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29	4,755,676	07-1988	Gaalema et al.	
	30	4,880,304	11-1989	Jaeb et al.	
	31	5,035,243	07-1991	Muz, Edwin	
	32	5,069,214	12-1991	Samaras et al.	
	33	5,131,391	07-1992	Sakai et al.	
	34	5,159,929	11-1992	Morris et al.	
	35	5,222,295	06-1993	Clarke et al.	
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	37	5,249,576	10-1993	Goldberger et al.	
	38	5,297,548	03-1994	Pologe, Jonas A.	
	39	5,319,355	06-1994	Russek	
	40	5,437,275	08-1995	Amundsen et al.	
	41	5,479,934	01-1996	Imran	
	42	5,482,034	01-1996	Lewis et al.	
	43	5,511,546	04-1996	Hon, Edward H.	
	44	5,534,851	07-1996	Russek	
	45	5,553,615	09-1996	Carim et al.	
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	48	5,752,914	05-1998	Delonzor et al.	
	49	5,792,052	08-1998	Isaacson et al.	
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	51	5,902,235	05-1999	Lewis et al.	
	52	6,049,727	04-2000	Crothall, Katherine D.	
	53	6,128,521	10-2000	Marro et al.	
	54	6,129,675	10-2000	Jay	
	55	6,144,866	11-2000	Miesel et al.	
	56	6,181,958	01-2001	Steuer et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when each U.S. Patent Document is attached. **ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/**

CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
SHEET 3 OF 7		Attorney Docket No. CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	57	6,181,958	01-2001	Steuer et al.	
	58	6,223,063	04-2001	Chaiken et al.	
	59	6,253,097	06-2001	Aronow et al.	
	60	6,301,493	10-2001	Marro et al.	
	61	6,317,627	11-2001	Ennen et al.	
	62	6,360, 113	03-2002	Dettling, Allen	
	63	6,430,437	08-2002	Marro	
	64	7,254,429	08-2007	Schurman et al.	
	65	7,657,294	02-2010	Eghbaletal.	
	66	7,657,295	02-2010	Coakley et al.	
	67	7,657,296	02-2010	Raridan et al.	
	68	7,761,127	07-2010	Al-Ali et al.	
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	70	7,764,982	07-2010	Dalke et al.	
	71	7,791,155	09-2010	Diab	
	72	7,801,581	09-2010	Diab	
	73	7,822,452	10-2010	Schurman et al.	
	74	7,844,313	11-2010	Kiani et al.	
	75	7,844,314	11-2010	Al-Ali	
	76	7,844,315	11-2010	Al-Ali	
	77	7,865,222	01-2011	Weber et al.	
	78	7,873,497	01-2011	Weber et al.	
	79	7,880,606	02-2011	Al-Ali	
	80	7,880,626	02-2011	Al-Ali et al.	
	81	7,891,355	02-2011	Al-Ali et al.	
	82	7,894,868	02-2011	Al-Ali et al.	
	83	7,899,507	03-2011	Al-Ali et al.	
	84	7,899,518	03-2011	Trepagnier et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
SHEET 4 OF 7		Attorney Docket No. CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	85	7,904,132	03-2011	Weber et al.	
	86	7,909,772	03-2011	Popov et al.	
	87	7,910,875	03-2011	Al-Ali	
	88	7,919,713	04-2011	Al-Ali et al.	
	89	7,937,128	05-2011	Al-Ali	
	90	7,937,129	05-2011	Mason et al.	
	91	7,937,130	05-2011	Diab et al.	
	92	7,941,199	05-2011	Kiani	
	93	7,951,086	05-2011	Flaherty et al.	
	94	7,957,780	06-2011	Lamego et al.	
	95	7,962,188	06-2011	Kiani et al.	
	96	7,962,190	06-2011	Diab et al.	
	97	7,976,472	07-2011	Kiani	
	98	7,988,637	08-2011	Diab	
	99	7,990,382	08-2011	Kiani	
	100	7,991,446	08-2011	Al-Ali et al.	
	101	8,000,761	08-2011	Al-Ali	
	102	8,008,088	08-2011	Bellott et al.	
	103	8,019,400	09-2011	Diab et al.	
	104	8,028,701	10-2011	Al-Ali et al.	
	105	8,029,765	10-2011	Bellott et al.	
	106	8,036,728	10-2011	Diab et al.	
	107	8,046,040	10-2011	Ali et al.	
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	111	8,050,728	11-2011	Al-Ali et al.	
	112	8,118,620	02-2012	Al-Ali et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
SHEET 5 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	113	8,126,528	02-2012	Diab et al.	
	114	8,128,572	03-2012	Diab et al.	
	115	8,130,105	03-2012	Al-Ali et al.	
	116	8,145,287	03-2012	Diab et al.	
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	119	8,180,420	05-2012	Diab et al.	
	120	8,182,443	05-2012	Kiani	
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	124	8,203,438	06-2012	Kiani et al.	
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	127	8,224,411	07-2012	Al-Ali et al.	
	128	8,228,181	07-2012	Al-Ali	
	129	8,229,533	07-2012	Diab et al.	
	130	6,636,759	10-2013	Robinson, Mark Ries	
	131	D326,715	06-1992	Schmidt, Michael	
	132	D356,870	03-1995	Ivers et al.	
	133	D378,414	03-1997	Allen et al.	
	134	D390,666	02-1998	Lagerlof, Ingemar	
	135	D403,070	12-1998	Maeda et al.	
	136	D414,870	10-1999	Saltzstein et al.	
	137	D452,012	12-2001	Phillips, Barney L.	
	138	D455,834	04-2002	Oonars et al.	
	139	D463,561	09-2002	Fukatsu et al.	
	140	D481,459	10-2003	Nahm, Werner	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
SHEET 6 OF 7		Attorney Docket No. CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	141	D502,655	03-2005	Huang, Chun-Mu	
	142	D508,862	08-2005	Behar et al.	
	143	D510,625	10-2005	Widener et al.	
	144	D514,461	02-2006	Harju, Jonne	
	145	D535,031	01-2007	Barrett et al.	
	146	D537,164	02-2007	Shigemori et al.	
	147	D547,454	07-2007	Hsieh, Chin-Chih	
	148	D549,830	08-2007	Behar et al.	
	149	D550,364	09-2007	Glover et al.	
	150	D551,350	09-2007	Lorimer et al.	
	151	D553,248	10-2007	Nguyen, Oiep Mong	
	152	D562,985	02-2008	Brefka et al.	
	153	D567,125	04-2008	Okabe et al.	
	154	D569,001	05-2008	Omaki, Koji	
	155	D569,521	05-2008	Omaki, Koji	
	156	D603,966	11-2009	Jones et al.	
	157	D621,516	08-2010	Kiani et al.	
	158	RE41,912	11-2010	Parker	
	159	RE42,753	09-2011	Kiani-Azarbayjany et al.	
	160	RE43,169	02-2012	Parker	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	161	http://www.masimo.com/rainbow/pronto.htm Noninvasive & Immediate Hemoglobin Testing, printed on August 20, 2009	
	162	http://www.masimo.com/pulseOximeter/Rad5.htm ; Signal Extraction Pulse Oximeter, printed on August 20, 2009	

Examiner Signature	Date Considered
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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i> SHEET 7 OF 7	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu, Chu Chuan
	Attorney Docket No.	CERCA.002C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	163	http://blogderoliveira.blogspot.com/2008_02_01_archive.html ; Ricardo Oliveira, printed on August 20, 2009	
	164	http://www.masimo.com/rad-57/ ; Noninvasive Measurement of Methemoglobin, Carboxyhemoglobin and Oxyhemoglobin in the blood. Printed on August 20, 2009	
	165	http://amivital.ugr.es/blog/?tag+spo2 ; Monitorizacion de la hemoglobina...y mucho mas, printed on August 20, 2009	
	166	http://www.masimo.com/spco/ ; Carboxyhemoglobin Noninvasive > Continuous > Immediate, printed on August 20, 2009	
	167	http://www.masimo.com/PARTNERS/WELCHALLYN.htm ; Welch Allyn Expands Patient Monitor Capabilities with Masimo Pulse Oximetry Technology, printed on August 20, 2009	
	168	http://www.masimo.com/pulseOximeter/PPO.htm ; Masimo Personal Pulse Oximeter, printed on August 20, 2009	
	169	http://www.masimo.com/generalFloor/system.htm ; Masimo Patient SafetyNet System at a Glance, printed on August 20, 2009	
	170	http://www.masimo.com/partners/GRASEBY.htm ; Graseby Medical Limited, printed on August 20, 2009	

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Examiner Signature	/Chu Chuan Liu/	Date Considered	04/10/2013
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu,Chu Chuan
SHEET 1 OF 2	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	5,441,054	08-1995	Tsuchiya	
	2	5,452,717	09-1995	Branigan et al.	
	3	6,636,759	10-2003	Robinson	
	4	2004/0039272	02-2004	Abdul-Hafiz et al.	
	5	2005/0162761	07-2005	Hargis et al.	
	6	2006/0167347	07-2006	Xu et al.	
	7	2006/0189859	08-2006	Kiani et al.	
	8	D551,350	09-2007	Lorimer et al.	
	9	D553,248	10-2007	Nguyen	
	10	D562,985	02-2008	Brefka et al.	
	11	D567,125	04-2008	Okabe et al.	
	12	D569,001	05-2008	Omaki	
	13	D569,521	05-2008	Omaki	
	14	2009/0105565	04-2009	Xu	
	15	7,606,606	10-2009	Laakkonen	
	16	2010/0049018	02-2010	Duffy et al.	
	17	6,278,889	08-2013	Robinson	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	18	PCT International Search Report, App. No. PCT/US2010/047899, Date of Actual Completion of Search: 01/26/2011, 4 pages.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu,Chu Chuan
SHEET 2 OF 2	Attorney Docket No.	CERCA.002C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	19	International Preliminary Report on Patentability and Written Opinion of the International Searching Authority issued in Application No. PCT US2009/049638, mailed January 5, 2011 in 9 pages.	
	20	European Office Action issued in application no. 10763901.5 on 01/11/2013.	

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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language translation is attached.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: Altman, Daniel E. KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference MLHUM008VPC	Date of mailing (day/month/year) 26 January 2011 (26-01-2011)
International application No. PCT/US2010/047899	International filing date (day/month/year) 3 September 2010 (03-09-2010)
Applicant MASIMO LABORATORIES, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see PCT Applicant's Guide, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**


The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide, National Chapters*.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer THOMAS, Roger Tel: +49 (0)89 2399-2247
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MLHUM008VPC	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2010/047899	International filing date (day/month/year) 03/09/2010	(Earliest) Priority Date (day/month/year) 03/09/2009
Applicant MASIMO LABORATORIES, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6b(a)).
c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 5
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☒ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/047899

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Embodiments of the present disclosure include an emitter driver configured to be capable of addressing substantially 2^N nodes with N cable conductors configured to carry activation instructions from a processor (402). In an embodiment, an address controller (502) outputs an activation instruction to a latch decoder (506) configured to supply switch controls to activate particular LEDs of a light source (418).

Form PCT/ISA/210 (continuation of first sheet (3)) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/047899

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/00 A61B5/1455 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/163775 A1 (BARRETT BRUCE J [US] ET AL) 25 June 2009 (2009-06-25)	8-14
Y	paragraphs [0002], [0003], [0016] - [0018] paragraphs [0027] - [0039]; figures 6-10	1-7, 15
X	US 2007/165218 A1 (QING XINLIN [US] ET AL) 19 July 2007 (2007-07-19)	8-14
Y	paragraphs [0003], [0005] paragraphs [0028] - [0036]; figures 3-9	1-7, 15
A	US 2007/293792 A1 (SLIWA JOHN W [US] ET AL) 20 December 2007 (2007-12-20) paragraphs [0023], [0060]; figures	1, 8, 15
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
11 January 2011		26/01/2011
Name and mailing address of the ISA/ European Patent Office, P.B. 5618 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Rosenblatt, Thomas

Form PCT/ISA/210 (second sheet) (April 2005)

CX-1622

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/047899

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009163775 A1	25-06-2009	WO 2009085822 A1	09-07-2009
US 2007165218 A1	19-07-2007	NONE	
US 2007293792 A1	20-12-2007	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/US2010/047899International filing date (day/month/year)
03.09.2010Priority date (day/month/year)
03.09.2009International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00 A61B5/1455Applicant
MASIMO LABORATORIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office

D-80298 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465Date of completion of
this opinionsee form
PCT/ISA/210

Authorized Officer

Rosenblatt, Thomas

Telephone No. +49 89 2399-8438



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2010/047899**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-7, 11-13, 15</u>
	No: Claims	<u>8-10, 14</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-15</u>
Industrial applicability (IA)	Yes: Claims	<u>1-15</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/047899

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2010/047899

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:
D1: US-A-2009/0163775,
D2: US-A-2007/0165218,
D3: US-A-2007/0293792.
- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 to 7 and 15 does not involve an inventive step in the sense of Article 33(3) PCT.
- 2.1 D1 is regarded as being the prior art closest to the subject-matter of claim 1, and discloses in Figure 6 in combination with Figures 7 to 11 a non-invasive physiological sensor (see paragraphs [0016,17]) configured to output one or more signals indicative of one or more physiological conditions of a patient being monitored, the sensor comprising:
 - a plurality of light emitting sources (18) configured for transmitting optical radiation to a measurement site;
 - one or more detectors (20,22) configured to output said one or more signals responsive to said optical radiation detected after attenuation by body tissue of said patient at said measurement site, said one or more signals indicative of said one or more physiological conditions of said patient.
- 2.2 The subject-matter of claim 1 therefore differs from this known sensor in that the sensor comprises a plurality of switches configured for selectively connecting one or more of the light emitting sources to one or more drive signals; and a decoder circuit (26) configured for controlling the plurality of switches, "wherein when said decoder circuit receives N inputs" (see also below item VIII) said decoder circuit configured to selectively address up to 2^N unique locations, each location including one or more of said plurality of said semiconductor switches, wherein activation of one of said unique locations causes at least one of said light emitting sources to transmit said optical radiation to said measurement site.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2010/047899

- 2.3 According to D1 the switches and decoder circuit are not comprised in the sensor but in an attached patient monitor and the number of unique locations to be addressed is $N \cdot (N-1)/2$, thus more limited (cf. paragraph [0018]). The problem to be solved may therefor be defined as increasing the number of switchable locations or light emitting sources to up to 2^N , when using N sensor signal inputs.
- 2.4 The solution defined in claim 1 does not involve an inventive step for the following reasons.
- 2.4.1 It is preliminarily noted, that N is not limited in the claim, so that the claim covers also embodiments for $N=1$ or $N=2$.
- 2.4.2 D2 discloses a similar sensor arrangement where an undefined number of monitoring elements (sensors, actuators, transducers, any type of sensor/ actuator may be used) shall be switched through a reduced number of control lines (304; 404; 704, 712; 804, 808; i.e. $N=1$ or 2), which correspond to the N inputs according to claim 1. These control lines are bundled together with one or two signal lines into a cable (cf. end of paragraph [0036]) connecting the sensor to a controller. The sensor comprises switches (308, 408, 708, 716, 812, 908) which switch on or off thereto connected sensor/actuator elements. It is clear, that each of these switches inherently must comprise an actual switch and a decoder unit, which decoder unit is able to decode the control signal generated by the controller containing the information as to which of the monitoring elements is to be switched on or off (see for example paragraph [0029]). Hence D2 teaches in order to limit the number of wires in a cable for switching a great number of sensor elements to 1 or 2 wires (without limit to 2^N sensor elements), to use an encoded control signal which is decoded in switches comprised in the sensor assembly, where each switch individually is activated depending on the control signal guided by the control line to the assembly, the switch of each sensor element implicitly comprising an actual switch element and a decoder unit. Hence, there is no "a decoder circuit for controlling the plurality of switches", rather a plurality of decoder circuits, and the number of sensor elements is not limited to 2^N .
- 2.4.3 The skilled person entrusted with the solution of the above identified technical problem would consider D2, because it relates to the same problem in the same technical field, and, applying its teaching to the device of D1, would arrive at a sensor with a number of decoder units, driven over one or two control lines. It is clear to the skilled person, that in order to further reduce costs and complexity of the sensor assembly, which is a common constraint in R&D, in particular if a large number of sensor elements is to be controlled, the

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2010/047899

individual decoder units would need to be integrated in a single decoder unit/ circuit which would then address the individual switches of each sensor element. The use of a single decoder circuitry in such cases may be considered as state of the art (for example D3, end of paragraphs [0023] and [0060]) at the date of filing of the present application. It appears that the limitation to 2^N sensor elements does not produce any particular technical effect and may only be considered as a constraint, which the skilled person would consider in the design of the sensor assembly if need is. There appears to be also no particular effect in the requirement of using N inputs controlling 2^N sensor elements. Also this appears only to be an additional design constraint which does not appear to involve any difficulty to be implemented if need is. Consequently, the combination of the teaching of D2 with the sensor known from D1, and carrying out further modifications belonging to the normal practice of the skilled person, obviously leads to a sensor assembly which falls under the scope of claim 1.

- 2.5 Dependent claims 2 to 7 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:
- 2.5.1 The additional features of the following claims are known from D1:
claim 2: see Figure 1;
claim 8: see Figure 7-8, symbols indicate to the skilled person LEDs.
- 2.5.2 Grouping of light emitting sources or sensor elements according to claim 5 is known from both D1 (Figures 9, 10, and corresponding passages) or D2 (Fig. 9), using different drive signals according to claim 6 at least from D1, Figure 10).
- 2.5.3 Consequently none of the additional features of these claims changes the finding presented under 2.4.
- 2.5.4 In claims 3 and 4 slight constructional changes in the sensor of claim 1 are defined which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.
- 2.6 The method according to claim 15 is implicitly carried out, when using a sensor according to claim 1. It consequently lacks inventive step for equivalent reasons as set out above for the subject-matter of claim 1.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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- 3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 8-10 and 14 is not new in the sense of Article 33(2) PCT.
- 3.1 Claim 8 is directed to a cable comprising as structural technical features only one or more signal lines and N address lines (see also item VIII below). The remaining functional features defined in the claim ("configured to carry...", "capable of selecting...") do not impose any further structural limitation on the cable itself. The cables known from D1 and D2 are suitable to be used for the same functions. Consequently the subject-matter of claim 8 is not new.
- 3.2 The cable used in Figures 7 and 8 of D2 comprises two signal lines. The cable is consequently anticipating the additional structural features of claims 9 and 10; the remaining functional statements in these claims do not limit the cable any further, so that also claims 9 and 10 lack novelty.
- 3.3 The additional features of claim 14 are no features of the actual cable, the cables known from D1 and D2 are suitable to be used for the functional definition of the claim, so that also this claim lacks novelty.
- 4 In claims 11 to 13 slight constructional changes in the cable of claim 8 are defined which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. In particular the provision of input and output connectors and flexible conduits belongs to the common knowledge of the skilled person. Integrating the decoder circuit in the cable, in particular in the output connector, also does not produce any unexpected technical effect. Consequently, the subject-matter of these claims lacks an inventive step (Article 33 (3) PCT).

Re Item VII**Certain defects in the international application**

- 5 The independent claims are not drafted in two-part form, contrary to Rule 6.3b) PCT.
- 6 The claims are not provided with reference signs, contrary to Rule 6.2b) PCT.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2010/047899

Re Item VIII**Certain observations on the international application**

- 7 The claims do not meet the requirement of Article 6 PCT, in that their subject-matter lacks clarity.
- 7.1 In claim 1 reference is made to "said semiconductor switches", whereas only a plurality of switches had been defined before. A doubt arises whether the same switches are meant.
- 7.2 The feature "wherein when said decoder circuit receives N inputs" is ambiguous. The term "input" may be understood as referring to a signal or to a physical entry. This ambiguity is confirmed when looking to claim 2, according to which input should be understood as referring to a signal. The above statement leaves it unclear whether the decoder has a single physical input, in the sense of an entry point, or N inputs. A single input may receive N input signals sequentially. However the description discloses decoder circuits only with N physical inputs, no sequential transmission is envisaged. The claim needs clarification.
- 7.3 Claim 8 relates to a cable and its signal and address lines. It comprises a number of functional definitions which do not clearly limit the structure of the claim. At least it is not clear whether the additional functional features of the N address lines "capable of selecting...", "configured to selectively...", and "thereby activating..." can be a limitation of the cable. It appears that these features are functions of a decoder circuit and not of a cable. At present these functional statements are not considered as structurally limiting the cable. Similar objections also apply to claims 9,10 and 14.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPEA (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference MLHUM.007VPC	FOR FURTHER ACTION See item 4 below	
International application No. PCT/US2009/049638	International filing date (<i>day/month/year</i>) 02 July 2009 (02.07.2009)	Priority date (<i>day/month/year</i>) 03 July 2008 (03.07.2008)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MASIMO LABORATORIES, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 05 January 2011 (05.01.2011)
	Authorized officer Athina Nickitas-Etienne e-mail: pt04.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/US2009/049638International filing date (day/month/year)
02.07.2009Priority date (day/month/year)
03.07.2008International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00Applicant
MASIMO LABORATORIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Ferrigno, Antonio

Telephone No. +31 70 340-2174



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2009/049638

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. **Additional comments:**

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2009/049638**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 22-53

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 22-53

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13^{ter}.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2009/049638**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-21

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>3-8</u>
	No: Claims	<u>1,2,9-21</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-21</u>
Industrial applicability (IA)	Yes: Claims	<u>1-21</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/049638

Re Item III.

Claims 22-53 not searched: see **Re Item IV** below.

Re Item IV.

The separate inventions/groups of inventions are:

1-21

physiological sensor with means to reduce thickness of body tissue

22-31

physiological sensor with a heat sink

32-38

heat sink of a medical sensor

39-46

conductive shield for a light sensitive detector

47-53

optical sensor comprising a noise shield

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

Document US2006/0211924 discloses (cf passages cited in the search report) the common features of claims 1 and 15. The remaining features are a bump as recited in claim 1, and a partially cylindrical lens as recited in claim 15. These features solve the problem of reducing thickness of body tissue and can be considered the first invention.

The subject-matter of claim 22 differs from the disclosure of document US2006/0211924 in that a heat sink is provided as recited in claim 22. This feature solves the problem of cooling the optical source and can be considered a second different invention.

The subject-matter of claim 32 is directed to an heat sink and doesn't have any feature in common with claims 1 and 15. It also doesn't have any feature in common with the subject-matter of claim 22, other than a "heat sink" (which is generally a known device). It solves the problem of providing an efficient heat sink and therefore can be

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/049638

considered a third different invention.

The subject-matter of claim 39 is directed to a conductive shield and doesn't have any feature in common with claims 1, 15, 22 and 32. It solves the problem of providing an efficient noise shielding device and therefore can be considered a fourth different invention.

Document US2006/0211924 discloses (cf passages cited in the search report) the common features of claims 1, 15, 22. and 47. Claim 47 provides the extra feature of a conductive shield. Claim 47 doesn't have any feature in common with claim 32. It also doesn't have any feature in common with claim 39, other than a "conductive shield" (which is generally a known device). The conductive shield, as recited in claim 47, solves the problem of protecting the sensor from noise interference and therefore can be considered a fifth different invention.

Re Item V.

1 Reference is made to the following documents:

- D1: US 2004/054291 A1 (SCHULZ CHRISTIAN [US] ET AL) 18 March 2004 (2004-03-18)
- D2: US-B1-6 345 194 (NELSON ROBERT S [US] ET AL) 5 February 2002 (2002-02-05)
- D3: WO 93/12712 A (VIVASCAN CORP [US]) 8 July 1993 (1993-07-08)

2 **INDEPENDENT CLAIM 1**

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document):

a noninvasive physiological sensor (1900, cf. paragraph 65 and figures 19A-D) for

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/049638

measuring one or more physiological parameters of a medical patient, the sensor comprising:

a light source (not shown in these figure; cf. paragraph 35 and claim 1);
a photodetector (not shown in these figure; cf. paragraph 35 and claim 1) operative to detect light from said light source after attenuation by body tissue of a medical patient and to generate a physiological signal responsive to the detected light, the physiological signal reflecting one or more physiological parameters of the medical patient (cf. paragraph 3); and
a bump (1920,1921) interposed between the light source and the photodetector, the bump protruding from a tissue contacting surface, the bump configured to reduce a thickness of the body tissue between the light source and the photodetector such that an optical pathlength between the light source and the photodetector is reduced (see spring 1910).

Hence, the subject-matter of claim 1 is disclosed in document D1.

2.2 The subject-matter of claim 1 is also disclosed in documents D2 and D3 (see corresponding passages cited in the search report: although the device disclosed in D2 is used for image mammography, it is also suitable to be used with other processing devices, and therefore for measuring one or more physiological parameters of a medical patient).

3 INDEPENDENT CLAIM 15

3.1 The bumps (1920,1921) disclosed in document D1 are partially cylindrical lenses (see paragraph 68). Hence, the same reasoning applies, mutatis mutandis, to the subject-matter of independent claim 15, which therefore is also considered not new.

4 DEPENDENT CLAIMS 2-14, 16-21

4.1 For the same reasons also the subject-matter of dependent claim 2 is considered not new.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/049638

- 4.2 The additional features of dependent claims 9, 10, 18-21 attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result (Article 6 PCT). However these features appear to be disclosed in document D1 (see passages cited in the search report). Hence, also the subject-matter of these claims is considered not new.
- 4.3 The additional features of dependent claims 11-14, 16, and 17 are also disclosed in document D1 (see passages cited in the search report). Hence, also the subject-matter of these claims is considered not new.
- 4.4 The additional features of dependent claims 3-8 are just some dimensional straightforward possibilities which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill (Articles 33(1) and 33(3) PCT).

Electronic Patent Application Fee Transmittal				
Application Number:	12829352			
Filing Date:	01-Jul-2010			
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS			
First Named Inventor/Applicant Name:	Jeroen Poeze			
Filer:	Scott Edward Raevsky/Khylo Rhoden			
Attorney Docket Number:	CERCA.002C1			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	15545495
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Scott Edward Raevsky/Gustavo Lopez
Filer Authorized By:	Scott Edward Raevsky
Attorney Docket Number:	CERCA.002C1
Receipt Date:	17-APR-2013
Filing Date:	01-JUL-2010
Time Stamp:	18:22:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$180
RAM confirmation Number	5587
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

Page 734 of 1082

Appx59012

CX-1622

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		002C1IDS.pdf	93904	yes	3
			ef8f77cefb05c776e149118ade0a87aec7e77124		
	Multipart Description/PDF files in .zip description				
	Document Description		Start		End
	Transmittal Letter		1		1
	Information Disclosure Statement (IDS) Form (SB08)		2		3
Warnings:					
Information:					
2	Non Patent Literature	ISRWO.pdf	991771	no	14
			f20a76e6299702e90cf3caa4d3b27389260f9869		
Warnings:					
Information:					
3	Non Patent Literature	IPRP.pdf	352211	no	9
			0668bfcfb5823d123918611f8bed947951af79306		
Warnings:					
Information:					
4	Non Patent Literature	EPOA.pdf	171017	no	4
			38f4bbe4aed26c9c23e190f13d0dd2055ea6e449		
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30674	no	2
			dc329e10a68af950972e4cdfaca17c07538283764		
Warnings:					
Information:					
Total Files Size (in bytes):			1639577		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Docket No.: CERCA.002C1

Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

Inventor	: Jeroen Poeze, et al.
App. No.	: 12/829352
Filed	: July 1, 2010
For	: MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	: Liu, Chu Chuan
Art Unit	: 3777
Conf. No.	: 8366

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a first office action, but before the mailing date of a final action and before the mailing date of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 16, 2013

By: /Scott Raevsky/
Scott Raevsky, Reg. No. 54,384
Attorney of Record
Customer No. 20995
(949) 721-7602

CERCA.002C1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Jeroen Poeze, et al.
App. No.	:	12/829,352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf No.	:	8366

RESPONSE TO OFFICE ACTION DATED NOVEMBER 23, 2012

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please reconsider the present Application in view of the amendments and remarks herein.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

Application No.: 12/829,352
Filing Date: July 1, 2010

AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A noninvasive sensor ~~capable of producing~~configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the sensor comprising:

an optical source configured to emit optical radiation onto said tissue at said measurement site;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output at least one respective signal stream responsive to said detected optical radiation;

a housing positioning said optical source and said at least one photodetector with respect to said measurement site;

a heat sink operably connected to said housing; and

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site.

2. **(Original)** The sensor of claim 1, wherein said tissue at said measurement site comprises a digit of said patient.

3. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is reusable.

4. **(Original)** The sensor of claim 1, wherein at least a portion of said housing is disposable.

5. **(Currently Amended)** The sensor of claim 1, comprising a cable connected to a patient monitor ~~capable of processing~~configured to process the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters.

6. **(Original)** The sensor of claim 5, wherein one of the one or more physiological parameters comprises total hemoglobin.

7. **(Original)** The sensor of claim 5, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

8. **(Original)** The sensor of claim 1, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation

Application No.: 12/829,352
Filing Date: July 1, 2010

by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

9. **(Original)** The sensor of claim 1, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

10. **(Currently Amended)** A method of measuring an analyte and a temperature at a measurement site of a living patient, said method comprising:

~~electronically~~ emitting optical radiation on the measurement site;

~~electronically~~ detecting said optical radiation after attenuation by tissue at the measurement site;

~~electronically~~ measuring the temperature of said measurement site;

using a signal processor, ~~electronically correcting wavelength drift from said optical source after attenuation by tissue of said measurement site~~ determining an indication of perfusion from said temperature measurement; and

~~electronically~~ determining an output measurement value indicative of the analyte based on the detected streams of optical radiation.

11. **(Currently Amended)** The method of claim 910, wherein said tissue at said measurement site comprises a digit of said patient.

12. **(Currently Amended)** The method of claim 910, wherein the method further comprises ~~electronically~~ correcting wavelength drift after attenuation by said tissue.

13. **(Currently Amended)** The method of claim 910, wherein said analyte comprises total hemoglobin.

14. **(Currently Amended)** A signal processing system ~~capable of producing~~ configured to produce a signal responsive to light attenuated by tissue at a measurement site on a patient, the system comprising:

a noninvasive optical sensor including:

an optical source configured to emit optical radiation onto said tissue at said measurement site;

at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and output

Application No.: 12/829,352
Filing Date: July 1, 2010

at least one respective signal stream responsive to said detected optical radiation;

a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site[.];

a monitor ~~capable of processing~~ configured to process the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters and determine an indication of perfusion of the tissue at the measurement site; and

a cable connected to the monitor providing communication between said optical sensor and said monitor.

15. **(Original)** The system of claim 14, wherein said tissue at said measurement site comprises a digit of said patient.

16. **(Original)** The system of claim 14, wherein at least a portion of said sensor is reusable.

17. **(Original)** The system of claim 14, wherein at least a portion of said sensor is disposable.

18. **(Original)** The system of claim 14, wherein one of the one or more physiological parameters comprises total hemoglobin.

19. **(Original)** The system of claim 14, wherein the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue.

20. **(Original)** The system of claim 14, wherein the sensor comprises plurality of photodetectors configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation.

21. **(Original)** The system of claim 14, wherein said optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm.

22. **(Original)** The system of claim 14, wherein said monitor comprises handheld monitor.

Application No.: 12/829,352
Filing Date: July 1, 2010

REMARKS

Applicant's thank the Examiner for the examination of the present Application. By way of summary, Claims 1-22 were pending. In the present Amendment, Applications have amended Claims 1, 5 and 10-14. Accordingly, Claims 1-22 remain pending for consideration.

Objection to Claims 10-14

The Office Action objected to Claims 10-14 for various informalities. Specifically, the Office Action objected to Claims 10 and 12 because it considered "electronically" to be a redundant term as used in these claims. Claims 11-13 were objected to for an improper dependency claim. Additionally, it was pointed out that Claim 12 would have a 112 4th issue if it depended from Claim 10.

In response, Applicants have amended Claims 10 and 12 to remove all instances of "electronically" as suggested by the Office Action. Applicants have also corrected the dependencies of Claims 11-13. Applicants note that the amendments discussed below to Claim 10 should alleviate any potential 112 4th paragraph issues. Accordingly, Applicants respectfully request withdrawal of the objections to the claims.

Rejection of Claims 1, 5 and 14 Under 35 U.S.C. § 112, 2nd Paragraph

The Office Action rejected Claims 1, 5 and 14 as being indefinite because these claims recited the language "capable of." Applicants respectfully traverse the rejection because "capable of" is not indefinite, nor does this language fail to positively recite a limitation. While Applicants traverse this rejection, Applicants have amended the language of Claims 1, 5 and 14 along the lines suggested by the Office Action in order to speed prosecution of the present Application. Accordingly, Applicants respectfully request withdrawal of the rejections to the claims.

Rejection of Claims 1-4 and 10-12 Under 35 U.S.C. § 102

The Office Action rejected Claims 1-4 and 10-12 as being anticipated by U.S. Pat. No. 5,362,966 to Rosenthal et al. (the Rosenthal patent). Applicants respectfully traverse this rejection. Specifically, Claim 1 has been amended, without prejudice or disclaimer, to recite a "heat sink" as part of the claimed sensor. The Rosenthal patent fails to disclose a heat sink as part of a sensor in combination with the other elements of Claim 1.

Application No.: 12/829,352
Filing Date: July 1, 2010

Claim 10 has been amended, without prejudice or disclaimer, to recite “using a signal processor, determining an indication of perfusion from said temperature measurement.” The Rosenthal patent does not disclose determining a perfusion indication from the temperature measurement.

Claims 2-4 and 11-12, which depend from Claims 1 and 10 respectively, are believed to be patentable for the same reasons discussed above with respect to Claims 1 and 10 respectively, and because of the additional limitations recited therein.

Rejection of Claims 5, 7-8, 14-17 and 19-20 Under 35 U.S.C. § 103

The Office Action rejected Claims 5, 7-8, 14-17 and 19-20 as being obvious over the Rosenthal patent in view of U.S. Pat. No. 6,353,750 issued to Kimura et al. (the Kimura patent). Applicants respectfully traverse this rejection for the following reasons.

Claims 5 and 7-8 depend from Claim 1 and are believed to be patentable for the same reasons discussed above with respect to Claim 1, and because of the additional limitations recited therein.

Claim 14 has been amended, without prejudice or disclaimer, to recite :a monitor configured to . . . determine output values for one or more physiological parameters and determine an indication of perfusion of the tissue at the measurement site.” The Rosenthal patent does not disclose determining a perfusion indication at the measurement site.

Claims 16-17 and 19-20 depend from Claim 14 and are believed to be patentable for the same reasons discussed above with respect to Claim 14, and because of the additional limitations recited therein.

Rejection of Claims 6, 9, 13, 18 and 21 Under 35 U.S.C. § 103

The Office Action rejected Claims 6, 9, 13, 18 and 21 as being obvious over the Rosenthal patent in view of the Kimura patent and further in view of U.S. Pat. No. 6,606,509 issued to Schmitt (the Schmitt patent). Applicants respectfully traverse this rejection for the following reasons.

Claims 6 and 9, Claim 13, and Claims 18 and 21, which depend from Claims 1, 10 and 14 respectively, are believed to be patentable for the same reasons discussed above with respect to Claims 1, 10 and 14 respectively, and because of the additional limitations recited therein.

Application No.: 12/829,352
Filing Date: July 1, 2010

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
CERCA.002A	12/534827	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	08/03/2009
CERCA.003A	12/534812	MULTI-STREAM SENSOR FRONT ENDS FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	08/03/2009
CERCA.004C1	13/525166	MULTI-STREAM SENSOR FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	06/15/2012
CERCA.005A	12/534825	MULTI-STREAM EMITTER FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS	08/03/2009
CERCA.006A	12/497528	NOISE SHIELDING FOR A NONINVASIVE DEVICE	07/02/2009
CERCA.007A	12/497523	CONTOURED PROTRUSION FOR IMPROVING SPECTROSCOPIC MEASUREMENT OF BLOOD CONSTITUENTS	07/02/2009
CERCA.008A	12/875062	EMITTER DRIVER FOR NONINVASIVE PATIENT MONITOR	09/02/2010

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	15019398
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Jarom D. Kesler/Erica Van Sciver
Filer Authorized By:	Jarom D. Kesler
Attorney Docket Number:	CERCA.002C1
Receipt Date:	21-FEB-2013
Filing Date:	01-JUL-2010
Time Stamp:	18:33:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		CERCA_002C1_Response.pdf	49131 403c44c1fb57806290ac3c3decaf8c3ac3e45be9	yes	8

CX-1622

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	4
	Applicant Arguments/Remarks Made in an Amendment	5	8
Warnings:			
Information:			
Total Files Size (in bytes):		49131	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>			

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
SHEET 1 OF 7	Examiner	Liu,Chu Chuan
	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	2002/0016536	02-2002	Benni, Paul	
	2	2002/0039272	04-2002	Abdul-Hafiz et al.	
	3	2002/0052547	05-2002	Toida, Masahiro	
	4	2002/0091322	07-2002	Chaiken et al.	
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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T¹ - Place a check mark in this area when an English language translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu,Chu Chuan
SHEET 2 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
(Multiple sheets used when necessary)	Examiner	Liu,Chu Chuan
SHEET 3 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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PTO/SB/08 Equivalent

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	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
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SHEET 4 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

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	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
SHEET 5 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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Examiner Signature	Date Considered
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	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
SHEET 6 OF 7	Attorney Docket No.	CERCA.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	161	http://www.masimo.com/rainbow/pronto.htm Noninvasive & Immediate Hemoglobin Testing, printed on August 20, 2009	
	162	http://www.masimo.com/pulseOximeter/Rad5.htm ; Signal Extraction Pulse Oximeter, printed on August 20, 2009	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i> SHEET 7 OF 7	Application No.	12/829352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	3777
	Examiner	Liu,Chu Chuan
	Attorney Docket No.	CERCA.002C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	163	http://blogderoliveira.blogspot.com/2008_02_01_archive.html ; Ricardo Oliveira, printed on August 20, 2009	
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Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Electronic Patent Application Fee Transmittal				
Application Number:		12829352		
Filing Date:		01-Jul-2010		
Title of Invention:		MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS		
First Named Inventor/Applicant Name:		Jeroen Poeze		
Filer:		Scott Edward Raevsky/Khylo Rhoden		
Attorney Docket Number:		CERCA.002C1		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

CX-1622

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

CX-1622

Electronic Acknowledgement Receipt	
EFS ID:	14997199
Application Number:	12829352
International Application Number:	
Confirmation Number:	8366
Title of Invention:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
First Named Inventor/Applicant Name:	Jeroen Poeze
Customer Number:	20995
Filer:	Scott Edward Raevsky/Christine Showalter
Filer Authorized By:	Scott Edward Raevsky
Attorney Docket Number:	CERCA.002C1
Receipt Date:	20-FEB-2013
Filing Date:	01-JUL-2010
Time Stamp:	18:43:36
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$180
RAM confirmation Number	9312
Deposit Account	111410
Authorized User	KNOBBE MARTENS OLSON AND BEAR
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

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Appx59035

CX-1622

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		002C1IDS.pdf	309374	yes	8
			63cc35c47faac85cb4292834cbb64488ee95f6c		
	Multipart Description/PDF files in .zip description				
	Document Description		Start		End
	Transmittal Letter		1		1
	Information Disclosure Statement (IDS) Form (SB08)		2		8
Warnings:					
Information:					
2	Non Patent Literature	PRONTO.pdf	1063205	no	2
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Warnings:					
Information:					
3	Non Patent Literature	Rad5.pdf	609883	no	2
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Warnings:					
Information:					
4	Non Patent Literature	OLIVEIRA.pdf	6827165	no	8
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Information:					
5	Non Patent Literature	RAD57.pdf	1350450	no	3
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Information:					
6	Non Patent Literature	SPO2.pdf	515558	no	2
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Information:					
7	Non Patent Literature	SPCO.pdf	1209301	no	2
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Warnings:					
Information:					
Page 758 of 1082					

CX-1622

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Information:					
9	Non Patent Literature	PPO.pdf	516438 e5ca59b34109a5fe7023a6644b99f91f097b95c	no	1
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Information:					
10	Non Patent Literature	SAFETYNET.pdf	2165479 b0aa2a782ed715e5cbd37a61ed893a954bb71959	no	2
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Information:					
11	Non Patent Literature	GRASEBY.pdf	483484 4bc584ce2c94c46a0b2c8c39e41ca14578d3af61	no	1
Warnings:					
Information:					
12	Fee Worksheet (SB06)	fee-info.pdf	30672 1de705cc1ec23fd0753fa1f54890f697ec4da778	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			15759267		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Docket No.: CERCA.002C1

Customer No. 20995

INFORMATION DISCLOSURE STATEMENT

Inventor	:	Jeroen Poeze, et al.
App. No.	:	12/829352
Filed	:	July 1, 2010
For	:	MULTI-STREAM DATA COLLECTION SYSTEM FOR NONINVASIVE MEASUREMENT OF BLOOD CONSTITUENTS
Examiner	:	Liu, Chu Chuan
Art Unit	:	3777
Conf. No.	:	8366

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

References and Listing

Submitted herewith in the above-identified application is an Information Disclosure Statement listing references for consideration. Copies of any listed foreign and non-patent literature references are being submitted.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a first office action, but before the mailing date of a final action and before the mailing date of a Notice of Allowance. This Statement is accompanied by the fees set forth in 37 C.F.R. § 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 20, 2013

By: /Scott Raevsky/
Scott Raevsky, Reg. No. 54,384
Attorney of Record
Customer No. 20995
(949) 721-7602

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CX-1622

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/829,352		Filing Date 07/01/2010		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)		SMALL ENTITY <input type="checkbox"/> OR		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)				
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =		OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =		OR	X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL		TOTAL					
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY OR		OTHER THAN SMALL ENTITY	
AMENDMENT	02/20/2013	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 22	Minus ** 22	= 0	X \$ =		OR	X \$62=	0	
	Independent (37 CFR 1.16(h))	* 3	Minus *** 3	= 0	X \$ =		OR	X \$250=	0	
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))							OR			
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
			TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0			
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY OR		OTHER THAN SMALL ENTITY	
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus **	=	X \$ =		OR	X \$ =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	X \$ =		OR	X \$ =		
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))							OR			
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR			
			TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE				
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>										

Legal Instrument Examiner:
/MARSHA RICHARDS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CX-1622



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/829,352	07/01/2010	Jeroen Poeze	CERCA.002C1	8366

20995	7590	11/23/2012
KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LIU, CHU CHUAN	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
11/23/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jayna.cartee@knobbe.com
 efiling@knobbe.com

Office Action Summary	Application No.		Applicant(s)	
	12/829,352		POEZE ET AL.	
	Examiner		Art Unit	
CHU CHUAN (JJ) LIU		3777		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 01 July 2010.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5) ☒ Claim(s) 1-22 is/are pending in the application.

5a) Of the above claim(s) ____ is/are withdrawn from consideration.

6) ☐ Claim(s) ____ is/are allowed.

7) ☒ Claim(s) 1-22 is/are rejected.

8) ☐ Claim(s) ____ is/are objected to.

9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 01 July 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/01/2010, 08/12/2010, 10/25/2011.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: ____.

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DETAILED ACTION

Claim Objections

1. Claim 10-14 are objected to because of the following informalities: In regard to claims 10 and 12, claims 10 and 12 recites steps of “electronically” emitting, detecting, measuring, correcting...etc. In most of the instances, emitting from a light source (unless of a chemical-luminescent nature) would be due to electronic elements being activated, and a detector/ photodetector is usually an electronic device (unless of using old fashioned film). A normal interpretation of emitting/detecting optical radiation as a claim step is trying to imply these were normally done electronically. Therefore if “electronically” is merely a redundant term, it should be deleted. In regard to claims 11-13, claims 11-13 should be dependent claims of claim 10 instead of claim 9. It is noted that if claim 12 depends from claim 10, claim 12 would have 112 4th issues because the limitations is recited in claim 10. In regard to claim 14, the period in the end of line 13 should be set forth a semi-colon; and “said housing” should be set forth “a housing”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 5 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to claims 1, 5 and 14, the limitation

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of “capable of ...” is not positively recited. It is suggested that the limitation should be set forth as “configured to” in order to positively claim the limitation(s).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal (USPN 5,362,966). In regard to claim 1, Rosenthal discloses a noninvasive sensor capable of producing a signal responsive to light attenuated by tissue at a measurement site on a patient (Col 1 line 1 - Col 2 line 41 and Fig. 1), the sensor comprising: an optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15) configured to emit optical radiation onto said tissue at said measurement site (Fig. 1); at least one photodetector (element 8, Fig. 1) configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (Fig. 1) and output at least one respective signal stream responsive to said detected optical radiation (through connection between element 8 and processor 10, Fig. 1); a housing positioning said optical source and said at least one photodetector with respect to said measurement site (element 28 in element 1, Fig. 1); a thermistor (element 29, Fig. 1) operably associated with said housing and configured to output a temperature signal

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responsive to a temperature of said measurement site (element 29, Fig. 1 and Col 2 lines 25-41).

In regard to claim 2, Rosenthal discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1).

In regard to claim 3, Rosenthal discloses at least a portion of said housing is reusable (element 1, Fig. 1).

In regard to claim 4, Rosenthal discloses at least a portion of said housing is disposable (element 20, Fig. 1).

In regard to claims 10 and 12, Rosenthal discloses a method of measuring an analyte and a temperature at a measurement site of a living patient (Fig. 1), said method comprising: electronically emitting optical radiation on the measurement site (elements 5 and 6, Fig. 1); electronically detecting said optical radiation after attenuation by tissue at the measurement site (element 8, Fig. 1); electronically measuring the temperature of said measurement site (element 29, Fig. 1); using a signal processor (element 10, Fig. 1), electronically correcting wavelength drift from said optical source after attenuation by tissue of said measurement site (Col 1 lines 26-63); and electronically determining an output measurement value indicative of the analyte based on the detected streams of optical radiation (glucose concentration, Col 1 lines 26-63).

In regard to claim 11, Rosenthal discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5, 7-8, 14-17, 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal as applied to claim 1 above, and further in view of Kimura et al. (USPN 6,353,750). In regard to claim 5, Rosenthal discloses a patient monitor (element 10, Fig. 1) capable of processing the at least one signal stream and the temperature signal to determine output values for one or more physiological parameters (Col 1 lines 26-63). Rosenthal does not specifically disclose the sensor comprises a cable connected to a patient monitor. Kimura teaches an optical sensor comprises a cable connected to a patient monitor for non-invasive blood constituent analysis (Figs. 1 and 2). It is known that a separate sensor structure is considered as much easier for performing regular maintenance such as cleaning the tissue containing section or for replacing sensor parts as compared to that in an integrated unit such as Fig. 1 of Rosenthal. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor (Rosenthal) to incorporate a separate sensor and a cable (Kimura) in order to provide an easy access for cleaning the tissue containing section / replacing sensor parts.

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In regard to claim 7, Rosenthal as modified by Kimura discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 lines 26-63 of Rosenthal).

In regard to claim 8, Rosenthal as modified by Kimura discloses the sensor comprises plurality of photodetectors (element 12, Fig. 1 and Col 5 lines 15-21 of Kimura) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal).

In regard to claim 14, Rosenthal as modified by Kimura discloses a signal processing system capable of producing a signal responsive to light attenuated by tissue at a measurement site on a patient (Fig. 1 of Rosenthal and Figs. 1 and 2 of Kimura), the system comprising: a noninvasive optical sensor (section 2, Fig. 1 of Rosenthal and element 1, fig. 2 of Kimura) including: an optical source configured to emit optical radiation onto said tissue at said measurement site (elements 5 and 6, Fig. 1 of Rosenthal); at least one photodetector configured to detect the optical radiation from said optical source after attenuation by said tissue of said patient (element 8, Fig. 1 of Rosenthal; element 12, Fig. 1 and Col 5 lines 15-21 of Kimura) and output at least one respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal and Figs 1 and 2 of Kimura); a thermistor operably associated with said housing and configured to output a temperature signal responsive to a temperature of said measurement site (element 29, Fig. 1 of Rosenthal); a monitor (element 10, Fig. 1

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of Rosenthal and element 2, Figs. 1 and 2 of Kimura) capable of processing the at least one signal stream and the temperature sensor to determine output values for one or more physiological parameters (Col 1 lines 26-63 of Rosenthal); and a cable connected to the monitor providing communication between said optical sensor and said monitor (cable 3, Fig. 2 of Kimura).

In regard to claim 15, Rosenthal as modified by Kimura discloses said tissue at said measurement site comprises a digit of said patient (Fig. 1 of Rosenthal and Fig. 2 of Kimura).

In regard to claim 16, Rosenthal as modified by Kimura discloses at least a portion of said sensor is reusable (element 1, Fig. 2 of Kimura).

In regard to claim 17, Rosenthal as modified by Kimura discloses at least a portion of said sensor is disposable (element 1, Fig. 2 of Kimura).

In regard to claim 19, Rosenthal as modified by Kimura discloses the thermistor measures the temperature of said measurement site to correct wavelength drift from said optical source after attenuation by said tissue (Col 1 line 1 - Col 2 line 41 of Rosenthal).

In regard to claim 20, Rosenthal as modified by Kimura discloses the sensor comprises plurality of photodetectors (element 12, Fig. 1 and Col 5 lines 15-21 of Kimura) configured to detect the optical radiation from said optical source (elements 5 and 6, Fig. 1 and Col 1 line 64 – Col 2 line 15 of Rosenthal) after attenuation by said tissue of said patient and each output a respective signal stream responsive to said detected optical radiation (Fig. 1 of Rosenthal).

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In regard to claim 22, Rosenthal as modified by Kimura discloses said monitor comprises handheld monitor (hand-held unit 1, Fig. 1 of Rosenthal).

8. Claims 6, 9, 13, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rosenthal and Kimura as applied to claims 1, 5, and 14 above, and further in view of Schmitt (USPN 6,606,509). In regard to claims 6, 13 and 18, Rosenthal as modified by Kimura discloses all the claimed limitations except the one or more physiological parameters comprises total hemoglobin. Schmitt teaches NIR wavelengths can be used to determine total hemoglobin concentration, hematocrit and water fraction of the finger (abstract; Col 7 lines 7-20; Fig. 6). Rosenthal as modified by Kimura discloses six or more IREDs can be utilized to measure a blood analyte from a finger (Col 1 line 64 – Col 2 line 13 and Fig. 1 of Rosenthal). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention was made to modify the sensor, system, and method (Rosenthal as modified by Kimura) to incorporate more NIR wavelengths (Schmitt) in order to obtain more physiological parameters of the tissue such as HBT, HCT or water fraction/ hydration information.

In regard to claims 9 and 21, Rosenthal as modified by Kimura and Schmitt discloses optical source is configured to emit optical radiation at least at wavelength between about 1600 nm and about 1700 nm (Col 7 lines 7-14 and Col 8 lines 34-48 of Schmitt).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHU CHUAN (JJ) LIU whose telephone number is (571)270-5507. The examiner can normally be reached on M-TH 8:00am~4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chu Chuan Liu/
Examiner, Art Unit 3777

/Eric F Winakur/
Primary Examiner, Art Unit 3777

Notice of References Cited	Application/Control No. 12/829,352	Applicant(s)/Patent Under Reexamination POEZE ET AL.	
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,362,966	11-1994	Rosenthal et al.	600/310
*	B	US-6,606,509	08-2003	Schmitt, Joseph M.	600/322
*	C	US-6,353,750	03-2002	Kimura et al.	600/344
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS


*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA			<input type="checkbox"/> T.D.			<input type="checkbox"/> R.1.47		
CLAIM		DATE									
Final	Original	11/01/2012									
	1	✓									
	2	✓									
	3	✓									
	4	✓									
	5	✓									
	6	✓									
	7	✓									
	8	✓									
	9	✓									
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	16	✓									
	17	✓									
	18	✓									
	19	✓									
	20	✓									
	21	✓									
	22	✓									

<i>Search Notes</i> 	Application/Control No. 12829352	Applicant(s)/Patent Under Reexamination POEZE ET AL.
	Examiner CHU CHUAN (JJ) LIU	Art Unit 3777

SEARCHED			
Class	Subclass	Date	Examiner
600	310, 316, 322, 323, 324, 326, 328, 331, 336, 340, 344, 473, 476	11/01/2012	CCL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search (PALM and EAST)	10/31/2012	CCL
EAST Search (TEXT, USPGPUB, USPAT) See Search History	11/01/2012	CCL
Google NPL Search	11/01/2012	CCL

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

/CHU CHUAN (JJ) LIU/
Examiner.Art Unit 3777

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829,352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	2877
SHEET 1 OF 1		Attorney Docket No. MLHUM.002C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	2004/049237	03-11-2004	Larson, et al.	
	2	2006/211924	09-21-2006	Dalke, et al.	
	3	4,258,719	03-31-1981	Lewyn	
	4	5,676,143	10-14-1997	Simonsen, et al.	
	5	6,172,743	01-09-2001	Kley, et al.	
	6	6,816,241	11-09-2004	Grubisic, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	7	WO 2000/25112	05-04-2000	Rolfe		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	8	International Search Report issued in Application No. PCT/US2009/052756, mailed February 10, 2009 in 14 pages.	
	9	International Preliminary Report on Patentability and Written Opinion of the International Searching Authority issued in Application No. PCT/US2009/052756, mailed February 8, 2011 in 8 pages.	

12086434
101211

Examiner Signature	/Chu Chuan Liu/	Date Considered	11/01/2012
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

T¹ - Place a check mark in this area when an English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/

Appx59053

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)		Examiner
SHEET 1 OF 9		Attorney Docket No. MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	7,734,320	06/2010	Al-Ali	
	2	7,729,733	06/2010	Al-Ali et al.	
	3	RE41,317	05/2010	Parker	
	4	D614,305	04/2010	Al-Ali et al.	
	5	D609,193	02/2010	Al-Ali et al.	
	6	7,647,083	01/2010	Al-Ali et al.	
	7	D606,659	12/2009	Kiani et al.	
	8	7,618,375	11/2009	Flaherty	
	9	2009-0259114	10/2009	Johnson et al.	
	10	7,596,398	09/2009	Al-Ali et al.	
	11	7,563,110	07/2009	Al-Ali et al.	
	12	7,530,955	05/2009	Diab et al.	
	13	7,530,949	05/2009	Al Ali et al.	
	14	7,530,942	05/2009	Diab	
	15	7,526,328	04/2009	Diab et al.	
	16	7,510,849	03/2009	Schurman et al.	
	17	7,509,494	03/2009	Al-Ali	
	18	7,509,154	03/2009	Diab et al.	
	19	7,500,950	03/2009	Al-Ali et al.	
	20	D587,657	03/2009	Al-Ali et al.	
	21	7,499,835	03/2009	Weber et al.	
	22	7,499,741	03/2009	Diab et al.	
	23	7,496,393	02/2009	Diab et al.	
	24	7,496,391	02/2009	Diab et al.	
	25	7,489,958	02/2009	Diab et al.	
	26	7,483,730	01/2009	Diab et al.	
	27	7,483,729	01/2009	Al-Ali et al.	
	28	7,471,971	12/2008	Diab et al.	
	29	7,471,969	12/2008	Diab et al.	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/

Appx59054

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 2 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	7,469,157	12/2008	Diab et al.	
	31	7,467,002	12/2008	Weber et al.	
	32	7,454,240	11/2008	Diab et al.	
	33	7,440,787	10/2008	Diab	
	34	7,438,683	10/2008	Al-Ali et al.	
	35	7,428,432	09/2008	Ali et al.	
	36	7,415,297	08/2008	Al-Ali et al.	
	37	7,383,070	06/2008	Diab et al.	
	38	7,377,899	05/2008	Weber et al.	
	39	7,377,794	05/2008	Al Ali et al.	
	40	7,376,453	05/2008	Diab et al.	
	41	7,373,194	05/2008	Weber et al.	
	42	7,373,193	05/2008	Al-Ali et al.	
	43	7,371,981	05/2008	Abdul-Hafiz	
	44	7,356,365	04/2009	Schurman	
	45	D566,282	04/2008	Al-Ali et al.	
	46	7,355,512	04/2008	Al-Ali	
	47	7,343,186	03/2008	Lamego et al.	
	48	7,341,559	03/2008	Schulz et al.	
	49	7,340,287	03/2008	Mason et al.	
	50	7,332,784	02/2008	Mills, et al.	
	51	7,328,053	02/2008	Diab et al.	
	52	7,295,866	11/2007	Al-Ali	
	53	7,292,883	11/2007	De Felice et al.	
	54	D554,263	10/2007	Al-Ali	
	55	7,289,835	10/2007	Mansfield et al.	
	56	7,280,858	10/2007	Al-Ali et al.	
	57	7,274,955	09/2007	Kiani et al.	
	58	7,272,425	09/2007	Al-Ali	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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Appx59055

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)		Examiner
SHEET 3 OF 9		Attorney Docket No. MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	59	7,254,434	08/2007	Schulz et al.	
	60	7,254,433	08/2007	Diab et al.	
	61	7,254,431	08/2007	Al-Ali	
	62	7,254,429	08/2007	Schurman et al.	
	63	7,245,953	07/2007	Parker	
	64	7,239,905	07/2007	Kiani-Azarbayjany et al.	
	65	RE39,672	06/2007	Shehada et al.	
	66	7,225,007	05/2007	Al-Ali	
	67	7,225,006	05/2007	Al-Ali et al.	
	68	7,221,971	05/2007	Diab	
	69	7,215,986	05/2007	Diab	
	70	7,215,984	05/2007	Diab	
	71	7,190,261	03/2007	Al-Ali	
	72	7,186,966	03/2007	Al-Ali	
	73	7,149,561	12/2006	Diab	
	74	7,142,901	11/2006	Kiani et al.	
	75	7,132,641	11/2006	Schulz et al.	
	76	2006-211924	09/2006	David Dalke, et al.	
	77	7,096,054	08/2006	Abdul-Hafiz et al.	
	78	7,096,052	08/2006	Mason et al.	
	79	7,067,893	06/2006	Mills et al.	
	80	7,044,918	05/2006	Diab	
	81	7,041,060	05/2006	Flaherty et al	
	82	7,039,449	05/2006	Al-Ali	
	83	7,030,749	04/2006	Al-Ali	
	84	7,027,849	04/2006	Al-Ali	
	85	7,024,233	04/2006	Ali et al.	
	86	7,015,451	02/2006	Dalke et al.	
	87	7,003,339	02/2006	Diab et al.	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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Appx59056

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 4 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	88	7,003,338	02/2006	Weber et al.	
	89	6,999,904	02/2006	Weber et al.	
	90	6,996,427	02/2006	Ali et al.	
	91	6,993,371	01/2006	Kiani et al.	
	92	6,985,764	01/2006	Mason et al.	
	93	6,979,812	12/2005	Al-Ali	
	94	6,970,792	11/2005	Diab	
	95	6,961,598	11/2005	Diab	
	96	6,950,687	09/2005	Al-Ali	
	97	6,943,348	09/2005	Coffin IV	
	98	6,939,305	09/2005	Flaherty et al.	
	99	6,934,570	08/2005	Kiani et al.	
	100	6,931,268	08/2005	Kiani-Azarbayjany et al.	
	101	6,920,345	07/2005	Al-Ali et al.	
	102	6,898,452	05/2005	Al-Ali et al.	
	103	6,861,639	03/2005	Al-Ali	
	104	6,852,083	02/2005	Caro et al.	
	105	6,850,788	02/2005	Al-Ali	
	106	6,850,787	02/2005	Weber et al.	
	107	6,830,711	12/2004	Mills et al.	
	108	6,826,419	11/2004	Diab et al.	
	109	6,822,564	11/2004	Al-Ali	
	110	6,816,741	11/2004	Diab	
	111	6,813,511	11/2004	Diab et al.	
	112	6,792,300	09/2004	Diab et al.	
	113	6,771,994	08/2004	Kiani et al.	
	114	6,770,028	08/2004	Ali et al.	
	115	6,760,607	07/2004	Al-Ali	
	116	6,745,060	06/2004	Diab et al.	

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

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Appx59057

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 5 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	117	6,735,459	05/2004	Parker	
	118	6,728,560	04/2004	Kollias, et al.	
	119	6,725,075	04/2004	Al-Ali	
	120	6,721,585	04/2004	Parker	
	121	6,721,582	04/2004	Trepagnier, et al.	
	122	RE38,492	04/2004	Diab et al.	
	123	6,714,804	03/2004	Al-Ali et al.	
	124	RE38,476	03/2004	Diab et al.	
	125	2004-054291	03/2004	Christian Schulz, et al.	
	126	6,699,194	03/2004	Diab et al.	
	127	6,697,658	02/2004	Al-Ali	
	128	6,697,657	02/2004	Shehada, et al.	
	129	6,697,656	02/2004	Al-Ali	
	130	6,684,091	01/2004	Parker	
	131	6,684,090	01/2004	Ali et al.	
	132	6,678,543	01/2004	Diab et al.	
	133	6,671,531	12/2003	Al-Ali et al.	
	134	6,661,161	12/2003	Lanzo et al.	
	135	6,658,276	12/2003	Diab et al.	
	136	6,654,624	11/2003	Diab et al.	
	137	6,650,917	11/2003	Diab et al.	
	138	6,643,530	11/2003	Diab et al.	
	139	6,640,116	10/2003	Diab	
	140	6,639,668	10/2003	Trepagnier, Pierre	
	141	6,632,181	10/2003	Flaherty et al.	
	142	6,606,511	08/2003	Ali et al.	
	143	6,597,933	07/2003	Kiani et al.	
	144	6,597,932	07/2003	Tian et al.	
	145	6,595,316	07/2003	Cybulski et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Appx59058

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 6 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	146	6,584,336	06/2003	Ali et al.	
	147	6,580,086	06/2003	Schulz et al.	
	148	6,542,764	04/2003	Al-Ali et al.	
	149	6,541,756	04/2003	Schulz et al.	
	150	6,526,300	02/2003	Kiani et al.	
	151	6,525,386	02/2003	Mills et al.	
	152	6,519,487	02/2003	Parker	
	153	6,515,273	02/2003	Al-Ali	
	154	6,505,059	01/2003	Kollias, et al.	
	155	6,501,975	12/2002	Diab et al.	
	156	6,470,199	10/2002	Kopotic et al.	
	157	6,463,311	10/2002	Diab	
	158	6,430,525	08/2002	Weber et al.	
	159	6,397,091	05/2002	Diab et al.	
	160	6,388,240	05/2002	Schulz et al.	
	161	6,377,829	04/2002	Al-Ali	
	162	6,371,921	04/2002	Caro et al.	
	163	6,368,283	04/2002	Xu, et al.	
	164	6,360,115	03/2002	Roger Greenwald, et al.	
	165	6,360,114	03/2002	Diab et al.	
	166	6,349,228	02/2002	Kiani et al.	
	167	6,345,194	02/2002	Robert Nelson, et al.	
	168	6,343,224	01/2002	Parker	
	169	6,334,065	12/2001	Al-Ali et al.	
	170	6,321,100	11/2001	Parker	
	171	6,285,896	09/2001	Tobler et al.	
	172	6,280,213	08/2001	Tobler et al.	
	173	6,278,522	08/2001	Lepper, Jr. et al.	
	174	6,263,222	07/2001	Diab et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Appx59059

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 7 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	175	6,256,523	07/2001	Diab et al.	
	176	6,241,683	06/2001	Macklem, et al.	
	177	6,236,872	05/2001	Diab et al.	
	178	6,232,609	05/2001	Snyder, et al.	
	179	6,229,856	05/2001	Diab et al.	
	180	6,206,830	03/2001	Diab et al.	
	181	6,184,521	02/2001	Coffin, IV et al.	
	182	6,165,005	12/2000	Mills et al.	
	183	6,157,850	12/2000	Diab et al.	
	184	6,152,754	11/2000	Gerhardt et al.	
	185	6,151,516	11/2000	Kiani-Azarbayjany et al.	
	186	6,144,868	11/2000	Parker	
	187	6,124,597	09/2000	Shehada	
	188	6,110,522	08/2000	Lepper, Jr. et al.	
	189	6,088,607	07/2000	Diab et al.	
	190	6,081,735	06/2000	Diab et al.	
	191	6,067,462	05/2000	Diab et al.	
	192	6,045,509	04/2000	Caro et al.	
	193	6,036,642	03/2000	Diab et al.	
	194	6,027,452	02/2000	Flaherty et al.	
	195	6,011,986	01/2000	Diab et al.	
	196	6,002,952	12/1999	Diab et al.	
	197	5,997,343	12/1999	Mills et al.	
	198	5,995,855	11/1999	Kiani et al.	
	199	5,940,182	08/1999	Lepper, Jr. et al.	
	200	5,934,925	08/1999	Tobler et al.	
	201	5,919,134	07/1999	Diab	
	202	5,904,654	05/1999	Wohltmann et al.	
	203	5,890,929	04/1999	Mills et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Appx59060

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
	Examiner	Unknown
SHEET 8 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	204	5,860,919	01/1999	Kiani-Azarbayjany et al.	
	205	5,833,618	11/1998	Caro et al.	
	206	5,830,131	11/1998	Caro et al.	
	207	5,823,950	10/1998	Diab et al.	
	208	5,810,734	09/1998	Caro et al.	
	209	5,791,347	08/1998	Flaherty et al.	
	210	5,785,659	07/1998	Caro et al.	
	211	5,782,757	07/1998	Diab et al.	
	212	5,769,785	06/1998	Diab et al.	
	213	5,760,910	06/1998	Lepper, Jr. et al.	
	214	5,758,644	06/1998	Diab et al.	
	215	5,743,262	04/1998	Lepper, Jr. et al.	
	216	Des. 393,830	04/1998	Tobler et al.	
	217	5,685,299	11/1997	Diab et al.	
	218	5,645,440	07/1997	Tobler et al.	
	219	5,638,818	06/1997	Diab et al.	
	220	5,638,816	06/1997	Kiani-Azarbayjany et al.	
	221	5,632,272	05/1997	Diab et al.	
	222	5,602,924	02/1997	Durand et al.	
	223	5,590,649	01/1997	Caro et al.	
	224	5,562,002	10/1986	Lalin	
	225	5,561,275	10/1996	Savage, et al.	
	226	5,533,511	07/1996	Kaspari et al.	
	227	5,494,043	02/1996	O'Sullivan et al.	
	228	5,490,505	02/1996	Diab et al.	
	229	5,482,036	01/1996	Diab et al.	
	230	D363,120	10/1995	Savage et al.	
	231	5,456,252	10/1995	Vari, et al.	
	232	5,452,717	09/1995	Branigan et al.	

Examiner Signature	Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /CCL/

Appx59061

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	Unknown
	Filing Date	Herewith
	First Named Inventor	Massi Joe E. Kiani et al.
	Art Unit	Unknown
(Multiple sheets used when necessary)	Examiner	Unknown
SHEET 9 OF 9	Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	233	D362,063	09/1995	Savage et al.	
	234	D361,840	08/1995	Savage et al.	
	235	D359,546	06/1995	Savage, et al.	
	236	5,431,170	07/1995	Mathews	
	237	D353,196	12/1994	Savage et al.	
	238	D353,195	12/1994	Savage et al.	
	239	5,278,627	01/1994	Aoyagi et al.	
	240	5,377,676	01/1995	Vari, et al.	
	241	5,341,805	08/1994	Stavridi, et al.	
	242	5,337,744	08/1994	Branigan	
	243	5,163,438	11/1992	Gordon et al.	
	244	5,069,213	12/1991	Polczynski	
	245	5,041,187	08/1991	Hink et al.	
	246	4,964,408	10/1990	Hink et al.	
	247	4,960,128	10/1990	Gordon et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	248	WO93/12712	07/1993	Vivascan Corp		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	249	International Search Report and Written Opinion for PCT/US2009/049638, mailed January 7, 2010.	

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Examiner Signature	/Chu Chuan Liu/	Date Considered	11/01/2012
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			

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Appx59062

CX-1622

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 1

Application No.	12/829,352
Filing Date	July 1, 2010
First Named Inventor	Kiani, et al.
Art Unit	2877
Examiner	Unknown
Attorney Docket No.	MLHUM.002C1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	4,267,844	05/19/1981	Yamanishi	
	2	4,655,225	04/07/1987	Dähne, et al.	
	3	4,781,195	11/01/1988	Martin	
	4	4,805,623	02/21/2989	Jöbsis	
	5	5,028,787	07/02/1991	Rosenthal, et al.	
	6	5,077,476	12/31/1991	Rosenthal	
	7	5,137,023	08/11/1992	Mendelson, et al.	
	8	5,337,745	08/16/1994	Benaron	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T ¹
	9	EP419223	03/27/1991	Minnesota Mining and Manufacturing Company		

NON PATENT LITERATURE DOCUMENTS

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	10	Burritt, Mary F.; Current Analytical Approaches to Measuring Blood Analytes; Vol. 36; No. 8(B); 1990	
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	15	Schmitt, Joseph M.; Simple Photon Diffusion Anaylsis of the Effects of Multiple Scattering on Pulse Oximetry; March 14, 1991; revised August 30, 1991	
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Examiner Signature	/Chu Chuan Liu/	Date Considered	11/01/2012
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EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	4	NIR and ("1600" "1650" "1700") adj nm and (total adj hemoglobin THB HBT) and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/11/01 09:21
S1	1	(12/829352).APP.	US-PGPUB; USPAT	OR	OFF	2012/10/31 07:11
S2	212	(Poeze near2 Jeroen Lamego near2 Marcelo Merritt near2 Sean Dalvi near2 Cristiano Vo near2 Hung Bruinsma near2 Johannes Lesmana near2 Ferdyan Kiani near3 Massi).in.	US-PGPUB; USPAT	OR	ON	2012/10/31 07:11
S3	37	(total adj hemoglobin THB) and shell and (finger digit appendage) and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/10/31 07:24
S4	36	S3 and temperature	US-PGPUB; USPAT	OR	ON	2012/10/31 07:26
S5	8	S4 and drift	US-PGPUB; USPAT	OR	ON	2012/10/31 07:27
S6	28	S3 and thermistor	US-PGPUB; USPAT	OR	ON	2012/10/31 07:33
S7	52	thermistor and temperature with skin and wavelength with (shift drift) and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/10/31 07:39
S8	0	S7 and (total adj hemoglobin THB)	US-PGPUB; USPAT	OR	ON	2012/10/31 08:00
S9	260	("20060211924" "5482036" "5997343" "6002952" "6027452" "6165005" "6263222" "6321100" "6345194" "6397091" "6542764" "6699194" "6714804" "6745060" "6816741" "6931268" "7027849" "7132641" "7225006" "7272425" "7274955" "7280858" "7377794" "7415297" "7454240" "7469157" "7483729" "7489958" "7496391" "7499835" "7734320" "D554263" "4258719" "5676143" "6816241" "4805623" "5137023" "5069213" "5452717" "5456252" "5561275" "5638816" "5833618" "6152754" "6232609" "6241683" "6606511" "6640116" "6661161" "6721585" "6792300" "6861639" "7039449" "7096052" "7186966" "7225007" "7239905" "7332784" "7340287" "7343186" "7356365" "7496393" "7596398" "7729733" "D353195" "D614305"	US-PGPUB; USPAT	OR	ON	2012/10/31 08:27

EAST Search History

CX-1622

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"7471969"	"7483730"	"7500950"
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EAST Search History

CX-1622

		"D566282" "D609193").PN.				
S10	14	S9 and thermistor	US-PGPUB; USPAT	OR	ON	2012/10/31 08:27
S11	272	NIR and (total adj hemoglobin THB)	US-PGPUB; USPAT	OR	ON	2012/10/31 08:51
S12	146	S11 and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/10/31 08:51
S13	2359	niwa.in.	US-PGPUB; USPAT	OR	ON	2012/10/31 09:09
S14	3	S13 and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/10/31 09:09
S15	484	thermistor and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/10/31 09:57
S16	322	S15 and (finger digit)	US-PGPUB; USPAT	OR	ON	2012/10/31 09:57
S17	250	("5077476").URPN.	USPAT	OR	ON	2012/10/31 11:54
S18	167	S17 and temperature	USPAT	OR	ON	2012/10/31 11:55
S19	58	S17 and temperature with skin	USPAT	OR	ON	2012/10/31 11:56
S20	10	S19 and 600/310-344.ccls.	USPAT	OR	ON	2012/10/31 12:05
S21	64	S16 and (drift shift) with wavelength	US-PGPUB; USPAT	OR	ON	2012/10/31 12:06
S22	26	("5362966").URPN.	USPAT	OR	ON	2012/10/31 12:16
S23	11	S22 and temperature with skin	USPAT	OR	ON	2012/10/31 12:16
S24	1	("7142901").PN.	US-PGPUB; USPAT	OR	OFF	2012/10/31 12:33
S25	461	S15 and temperature	US-PGPUB; USPAT	OR	ON	2012/10/31 12:44
S26	241	S25 and temperature with (skin site area)	US-PGPUB; USPAT	OR	ON	2012/10/31 12:45
S27	163	S26 and (shift\$4 drift\$4)	US-PGPUB; USPAT	OR	ON	2012/10/31 12:45
S28	38	robinson.in. and 600/310-344.ccls.	US-PGPUB; USPAT	OR	ON	2012/10/31 12:58
S29	1	("20080242958").PN.	US-PGPUB; USPAT	OR	OFF	2012/10/31 13:14
S30	53	S9 and temperature	US-	OR	ON	2012/10/31

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			PGPUB; USPAT			13:16
S31	2360	600/310-344.ccls. and temperature	US- PGPUB; USPAT	OR	ON	2012/10/31 13:34
S32	338	S31 and clip and finger	US- PGPUB; USPAT	OR	ON	2012/10/31 13:54
S33	115	S32 and thermistor\$1	US- PGPUB; USPAT	OR	ON	2012/10/31 14:06
S34	4	fourth adj wavelength and 600/310-344.ccls. and cable and monitor and (total adj hemoglobin THB HBT)	US- PGPUB; USPAT	OR	ON	2012/11/01 07:38
S35	223	finger and wavelengths and 600/310-344.ccls. and cable and monitor and (total adj hemoglobin THB HBT)	US- PGPUB; USPAT	OR	ON	2012/11/01 07:42
S36	45	S35 and NIR	US- PGPUB; USPAT	OR	ON	2012/11/01 07:45
S37	0	S36 and "1600" adj nm	US- PGPUB; USPAT	OR	ON	2012/11/01 07:53
S38	4	NIR and "1600" adj nm and (total adj hemoglobin THB HBT) and 600/310-344.ccls.	US- PGPUB; USPAT	OR	ON	2012/11/01 07:54
S39	1	("6353750").PN.	US- PGPUB; USPAT	OR	OFF	2012/11/01 08:07

EAST Search History (Interference)

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Multiple sheets used when necessary)</i>	Application No.	12/829,352
	Filing Date	July 1, 2010
	First Named Inventor	Jeroen Poeze
	Art Unit	2877
SHEET 1 OF 1		Attorney Docket No. MLHUM.002C1

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Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	2004/049237	03-11-2004	Larson, et al.	
	2	2006/211924	09-21-2006	Dalke, et al.	
	3	4,258,719	03-31-1981	Lewyn	
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	7	WO 2000/25112	05-04-2000	Rolfe		

NON PATENT LITERATURE DOCUMENTS

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	8	International Search Report issued in Application No. PCT/US2009/052756, mailed February 10, 2009 in 14 pages.	
	9	International Preliminary Report on Patentability and Written Opinion of the International Searching Authority issued in Application No. PCT/US2009/052756, mailed February 8, 2011 in 8 pages.	

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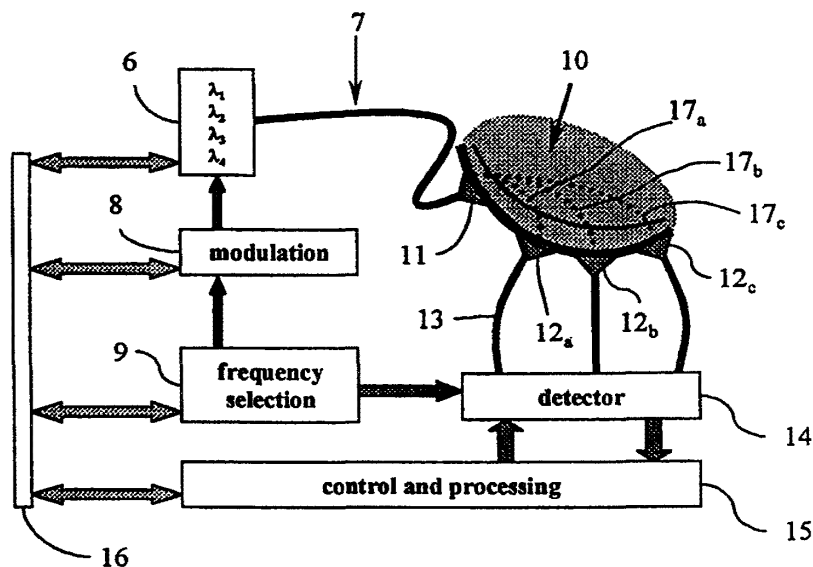
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(21) International Application Number: PCT/GB99/03563 (22) International Filing Date: 28 October 1999 (28.10.99) (30) Priority Data: 9823452.9 28 October 1998 (28.10.98) GB (71)(72) Applicant and Inventor: ROLFE, Peter [GB/GB]; Daisy Lake, Oakley, Market Drayton, Shropshire TF9 2QW (GB). (74) Agent: ABRAMS, Michael, John; Haseltine Lake & Co., Imperial House, 15-19 Kingsway, London WC2B 6UD (GB).		(81) Designated States: CN, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: OPTICAL MONITORING**(57) Abstract**

An optical monitoring method is disclosed by means of which the absolute concentration of chemical or biological species of interest may be determined in tissue *in vivo*. Electromagnetic radiation – typically near infrared – is directed through the tissue of interest and emergent radiation is sampled from at least three points with different direct physical path lengths. Signal processing in real time is applied to the emergent radiation. Apparatus for use in this method is also disclosed.



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Optical Monitoring

This invention is concerned with improvements to methods used for non-invasive monitoring of patients using electromagnetic energy.

5 It is desirable to obtain indications of the concentrations of certain chemicals in various parts of the body in order to detect abnormal and dangerous conditions. Examples of chemicals of interest include those which are linked to the transport or utilisation of oxygen, such as oxy and de-oxy haemoglobin in blood, oxy and de-oxy myoglobin in muscle or oxidised and reduced intra-cellular enzymes such as cytochrome aa₃. Other chemicals of interest include glucose in blood or tissue or
10 cholesterol in blood.

The purpose of determining such chemical concentrations is to allow correction of abnormal and dangerous conditions and it is therefore desirable to carry out repeated measurements or continuous real-time measurements. This is particularly desirable when measuring those chemicals linked to transport or utilisation of
15 oxygen because the concentrations of these are known to be liable to change very rapidly; significant changes can occur in 5-10 seconds.

In order for abnormal and dangerous conditions to be determined it is also necessary for the measurement of chemical concentration to be made in a quantitative way so that comparison with accepted normal values might be made.

20 It is known that electromagnetic energy can pass through tissue and that when wavelengths in the near infra-red region of the spectrum are used then deeper penetration of tissues is possible as compared to that achieved with visible wavelengths.

It is also known that by interrogating tissue with two or more specific wavelengths of

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electromagnetic energy, followed by mathematical analysis of the intensity of the energy emerging from passage through the tissue, it is possible to determine estimates of the changes in concentration of one or more chemical species in the tissue being interrogated. In order to perform the calculation use is made of the Beer-Lambert law. Here it is given for a single absorber and a single wavelength of measurement.

$$A_I = \log \frac{\mathcal{I}_0}{\mathcal{I}} = e_I C_I d_p \zeta + \Psi \quad \text{Equation 1}$$

in which A_I is the **attenuation** of the electromagnetic wave measured in optical density units (OD), \mathcal{I}_0 is the incident wave intensity, \mathcal{I} is the intensity of the wave emerging from the tissue, e_I is the **specific extinction coefficient** of the absorbing compound in $\mu\text{molar}^{-1} \cdot \text{cm}^{-1}$, C_I is the **concentration** of the absorbing compound and d_p is the **distance** in cm between the points where the wave enters and emerges from the tissue. Due to scattering of the electromagnetic wave in tissue its path will be longer than the physical spacing by a **factor** ζ , known as the **scattering factor**. Attenuation of the wave also occurs due to scattering and an **additive term**, Ψ , is used to describe this. It is useful to consider the product $e \cdot C$ as the **absorption coefficient**, μ_a .

Problems arise with this method of monitoring chemical variables in patients because it is not possible to determine absolute chemical concentration. This is partly because the scattering factor, ζ , is not known and partly because the additive term, Ψ , is not known. Instead of calculating absolute chemical concentration, therefore, it is now common practice to measure changes in attenuation from an arbitrary starting point and from such changes in attenuation to calculate changes in chemical concentration.

Although in some circumstances this current method can provide useful information for the monitoring of patients it is a disadvantage that it is not possible to determine

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absolute quantitative values of the chemical concentrations. This means that measurements made in one subject can not be compared with those made in another subject and measurements made in one subject on one occasion can not be compared with measurements made in that subject on a second or subsequent occasion.

The absolute chemical concentrations can be determined if certain effects of scattering can be measured and if other certain effects of scattering can be modelled mathematically and if these steps can be performed rapidly and cost-effectively. This approach is the essence of the present invention.

As indicated in equation 1, one effect of scattering in tissues is that the length of the path travelled by the interrogating wave is greater than the physical distance, d_p . In fact the so-called optical pathlength, d_o is greater than d_p by something like 3 to 5 times depending on the tissue type and the wavelength of light.

This effect of scattering could be taken into account if d_o could be measured. It is known that there are at least two methods to measure optical path length.

Firstly, the time taken for a short pulse of electromagnetic energy at the appropriate wavelength to travel through the tissue can be measured and distance then calculated as:

$$d_o = c.t$$

Equation 2

where c is the velocity of light in the tissue and t is the time taken for passage of the short pulse through the tissue. Due to the high speed of light the value of t is very short for tissue path lengths of a few cms and so there are practical problems in its measurement. It is known that very short pulses of infra-red light, in the order of a

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few psecs, can be produced by means of lasers and it is also known that such short pulses can be detected by a streak camera and these devices may be used together to measure optical path length in human tissues. However, this apparatus is large, costly, and can not be used in routine clinical circumstances.

- 5 A second method to measure optical pathlength in tissue is based on the modulation, for example with a sinusoidal function, of the intensity of the light beam passed into the tissue. In this case the intensity of the light emerging from the tissue will also vary sinusoidally but the phase of this intensity variation will lag that of the incident beam by an amount that is proportional to the optical pathlength.
- 10 Thus measurement of the phase shift between the incident and detected beams will allow optical pathlength to be calculated.

- Complications arise in practice due to the multiplicity of scattering events in tissue. This situation leads to a multiplicity of optical paths, each producing a corresponding phase-shift. The resulting received optical intensity therefore
- 15 contains a summation of phase-shifted components representing the group of scattered paths. In order to derive a useful estimate of optical path length, for example the mean, the received wave intensity must be analysed rapidly in order that the estimate may be used to provide continuous real-time calculations of chemical concentration.

- 20 The phase-shift method can be implemented easily, and at comparatively low cost, when the object under investigation contains relatively few scattering discontinuities. Under these circumstances there is a small number of scattering paths, and the summated signal at the receiver may be analysed using high frequency phase sensitive circuits. However, tissue of interest such as the brain,
- 25 limbs, liver, kidneys, muscle, bone all scatter significantly and in thick sections there will be substantial attenuation of the incident wave as well as multiple-path mixing contained in the received signal.

According to one aspect of the present invention, there is provided a method of

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determining the concentration of a selected chemical or biological species *in vivo*, in which electromagnetic radiation is directed through the tissue and emergent radiation is analysed, the frequency of the radiation being selected so as to correspond to a known absorption frequency for the species of interest and the radiation applied to the tissue being intensity modulated in accordance with a predetermined mathematical function, characterised in that:

(i) emergent radiation is received by detectors positioned in at least three locations, each of which has a different linear separation from the radiation input;

(ii) emergent radiation detected by said detectors is subjected to signal processing to determine, in real time, (a) the mean optical path lengths for each detector at each input wavelength; and (b) the attenuation of the input radiation at each detector and for each input wavelength; and

(iii) the concentration of the species of interest in the tissue is calculated using known specific extinction coefficients for the species of interest at the wavelengths used and the mean optical path length and attenuation data derived from the input and emergent radiation by the signal processing step.

With preferred embodiments of the present invention there is provided means whereby an electromagnetic wave is modulated before being passed into tissue and the corresponding signals collected at three or more points after passage into and out of tissue segments containing phase information related to group optical pathlength properties are processed quickly in real-time in order to recover optical path length estimates for use in the calculation of absolute chemical concentration. There is further provided means with which phase-shifted modulation components of light propagated through tissue are analysed quickly in real-time in order to allow the attenuation due to scattering phenomena as specified by the additive term, Ψ , in equation 1 to be derived.

Subsequent combination of the two components of the information derived by the two aspects of the invention then allows calculation of absolute concentrations of

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specific chemicals within the tissue under interrogation having value for medical diagnosis or therapy.

According to a second aspect of the present invention, there is provided pparatus for use in determining the concentration of a selected chemical or biological species *in vivo*, which comprises:

5

(a) a plurality of laser diodes;

(b) a modulation circuit arranged to modulate the outputs of said laser diodes at two or more modulation frequencies;

(c) a frequency selection circuit arranged select said modulation frequencies;

10

(d) means for inputting the modulated laser radiation into human or animal tissue which is to be examined;

(e) at least three detectors for attachment to said human or animal to receive radiation emergent from said tissue; and

15

(f) signal processing means for processing data derived from said detectors, said modulation circuit and said frequency selection circuit.

One embodiment of the present invention is now described purely for illustrative purposes with reference to the accompanying drawings, in which:

Figure 1 illustrates the passage of an optical beam through animal tissue; and

Figure 2 is a schematic illustration of apparatus in accordance with this invention.

20

Referring to the drawings, Figure 1 shows a beam of electromagnetic energy [1] that has been modulated with a specific function. It will be known to those skilled in this branch of science that such energy may be considered either as a wave or as particle-like photons. The energy passes through tissue [2] that has both scattering and absorbing properties. Specific optical absorption may take place by particular

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chemical constituents in the tissue and of interest in the care of patients is the optical absorption due to the chemicals oxy-haemoglobin and deoxy-haemoglobin and the concentration of each of these chemicals individually or as some form of scaled ratio is required. There is also interest in the specific optical absorption by the intra-cellular enzyme cytochrome oxidase which may exist in the oxidised or reduced form and is known to have particular optical absorption bands in the near infra-red part of the electromagnetic spectrum for each of these two states.

The energy emerging after propagation through the tissue [3] will have been transformed by the transfer function of the tissues, including absorption by haemoglobin in its two forms and cytochrome oxidase in its oxidised and reduced state and by scattering events. The transfer function of the tissues is given by the output/input ratio, $\mathcal{I}/\mathcal{I}_0$,

Extraction and analysis of the transfer function is achieved in the present invention and this is then used in the calculation of the absorption coefficient, μ_a , and so-called reduced scattering coefficient, μ_s' , of the tissue.

Figure 2 provides a schematic description of an instrument constructed in accordance with the present invention. In order to calculate the absolute concentrations of haemoglobin in its two forms the electromagnetic energy transmitted into the tissue consists of time-multiplexed beams of two or more wavelengths, λ_m , between 700 nm and 900 nm. In this particular embodiment of the present invention this is achieved by switching laser diodes [6] on and off in sequence and combining the laser diode outputs and conveying the combined energy by means of an optical fibre bundle [7] and an attachment probe [11].

During the laser ON period the intensity of the laser-generated light is modulated by a function, f_m , by means of a modulation circuit [8]. The modulation function may be sinusoidal having a frequency of ν_m . Two or more modulating frequencies are used, ν_{m1} , ν_{m2} , etc. The actual values for the present clinical applications are in the range 50 MHz to 500 MHz and are determined by a frequency selection circuit [9].

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Electromagnetic energy propagates through the tissue of interest [10] according to the structure and composition of the tissue. The energy will pass through different regions of the tissue and examples of particular paths are shown as 17_a, 17_b and 17_c. Having propagated into the tissue of interest the energy is collected at three or
 5 more points by means of attachments [12_a, 12_b, 12_c], which may be connected to the signal processing elements of the system by spatially separate optical fibres; alternatively, the individual optical fibres may be bundled together for convenience.

The spacing between the input point, [11], and the collection points, [12_a, 12_b, 12_c], has some significance. The corresponding physical pathlengths, $(d_p)_a$, $(d_p)_b$ and $(d_p)_c$
 10 are chosen such that there is sufficient penetration of the deeper tissue regions by electromagnetic wave paths 17_a, 17_b and 17_c. In human tissues this means that $(d_p)_a$ should be greater than 2.8 cms., $(d_p)_b$ should be greater than $(d_p)_a$ and $(d_p)_c$ should be greater than $(d_p)_b$.

In a preferred arrangement the collected energy is transported by individual optical
 15 fibres such as [13] to a photomultiplier where it is detected and amplified [14]. An alternative arrangement may use an array of detector sensors fixed directly to the tissue surface.

With the preferred arrangement n_m , v_m , etc. With this arrangement the signal output of the photomultiplier consists of the low frequency spectrum of 10kHz to
 20 15kHz rather than the comparatively high frequency modulating frequency of 50 to 500 MHz and is therefore more straightforward to process. The detected optical signal contains phase shifts related to optical pathlength and intensity information in the form of a depth of modulation related to attenuation.

Whilst the heterodyne method is the preferred approach the present invention may
 25 also be realised using well-known homodyne detection.

Mean optical path length at each wavelength and for each detector position is calculated within a control and processing unit [15] by determining the phase shift of the modulating signal. Firstly, a single modulating frequency is used and optical path

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length and modulation depths are determined for each detector position. Then, for a single detector position path length and modulation depth are determined for each of the two or more frequencies of modulation.

5 Phase shifts due to multiple optical path lengths are determined by performing a Fast Fourier Transform (FFT) within the control and processing unit [15] on the spectrum of signals available at the output of the detector unit [14]. An important aspect of the particular embodiment of the invention which facilitates accurate phase measurement is the arrangement of the control and processing unit and the specific instrument modules (6, 8, 9 and 14) which includes the use of a data and control bus.

10 The analysis of the phase-shift information from the FFT provides statistical data relating to the scattering properties of the tissue under interrogation.

In order to calculate the concentrations of oxy-haemoglobin, $\{\text{HbO}_2\}$, and de-oxy haemoglobin, $\{\text{Hb}\}$, use is made of the known approaches to electromagnetic wave transport based on the so-called diffusion approximation. This is modelled within the instrument and the approximation allows relationships to be derived between, firstly, 15 phase shift and ν_m , μ_s' , μ_m and d_p at each wavelength, λ_n , of the interrogating electromagnetic wave and, secondly, the modulation depth and ν_m , μ_s' , μ_m and d_p at each wavelength, λ_n . The specific measurements made by the instrument designed according to the present invention are used with the diffusion approximation in order 20 to calculate the two unknowns, μ_s' and μ_m for each wavelength, λ_n . The wavelength dependent values of the extinction coefficients for HbO_2 and Hb are known. Use of these together with the calculated values of μ_s' and μ_m for each wavelength, λ_n , then allows the absolute concentrations of $\{\text{HbO}_2\}$ and $\{\text{Hb}\}$ to be calculated.

For clinical convenience the measurements of $\{\text{HbO}_2\}$ and $\{\text{Hb}\}$ are used to derive the 25 ratio $\{\text{HbO}_2\}/[\{\text{Hb}\}+\{\text{HbO}_2\}]$ which is then expressed as a percentage by multiplication by 100 in order to produce a measurement of absolute oxygen saturation. The instrument described here as representing one embodiment of the present invention incorporates this feature.

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The continuous real-time monitoring of oxy-haemoglobin, $\{\text{HbO}_2\}$, and de-oxy haemoglobin, $\{\text{Hb}\}$, with the present invention also allows automatic correction of abnormal and dangerous levels to be achieved. For this purpose, the output of the instrument disclosed in Fig 2 is used as an input to a process control loop, the output of which is used to adjust the concentration of oxygen in the gas supply to the patient.

Description of Operation of the Instrument

In order to perform measurements on a subject using the instrument firstly probes 11 and $[12_a, 12_b, 12_c]$ must be affixed with appropriate spacing between the input point and the collection points. For example, for examination of the brain $(d_p)_a$ should typically be 3 cm. In this case $(d_p)_b$ will then be 3.8 cm and $(d_p)_c$ will be 4.6 cm. Attachment probes 11 and $[12_a, 12_b, 12_c]$ should also lie in a straight line.

According to the present invention the instrument will then perform a sequence of operations in order to derive quantitative values for chemical concentrations. If we consider here the measurement of O_2Hb , HHb and oxidised cytochrome aa₃, three optical wavelengths, typically 760nm, 840nm and 905nm, will be required. The currently preferred sequence of operation will be:

1. Three laser diodes [6] will be switched on and off sequentially at a repetition rate of typically 1 kHz.
2. The laser ON period is divided into two parts. During the first part of the laser ON period a modulating signal of ν_{m1} is applied to the laser. The frequency of ν_{m1} may be typically 100 MHz. During the second part of the laser ON period a second modulating signal, ν_{m2} , is applied to the laser. The frequency of ν_{m2} can be 140 MHz.

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3. Energy collected at $[12_a, 12_b, 12_c]$ during the laser ON period is fed either to a multiplexed detector, typically a photomultiplier type R6357; or to three parallel photomultipliers; or to three silicon detectors. The photomultiplier(s) will preferably have dynode drive at a frequency offset firstly from ν_{m1} and, secondly, from ν_{m2} by an amount which is typically 10 kHz and will thus produce an output by the heterodyne principle. If silicon detectors are used then the outputs will be mixed with a reference signal derived from ν_{m1} and ν_{m2} in order to produce the desired output.
4. Steps 2 and 3 are repeated for each of the laser diodes in sequence.
5. The output values produced in step 3 are used to calculate the transfer function of the interrogated tissue at each wavelength. This then allows expressions for scattering factor, ζ and additive term, Ψ , to be determined. Application of the Beer-Lambert law then allows μ_a and μ_s' to be determined..
6. Based on a second aspect of the invention the output values produced in steps 3 and 4 for each collector position are used to calculate the slope values S_{dc} , S_{ac} and S_{phase} for the DC, AC and phase expressions derived from the Diffusion Approximation of the transport equation. (For description of the Diffusion Approximation see, for example, *A Ishimaru "Diffusion of light in turbid material", Applied Optics, vol 28: 2210-2215, 1989*; the content of this document is incorporated herein reference thereto). The instrument then calculates values for μ_a and μ_s' from the slope expressions.
7. The values for μ_a and μ_s' derived either as in 5 or in 6 then allow the concentrations of O₂Hb, HHb and oxidised cytochrome aa₃ to be calculated.
8. Selection of different wavelengths for the interrogating energy allows determination of the concentrations of other chemical species provided their molar extinction coefficients are known and are spectrally unique.

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To achieve "proof of principle" certain practical experiments have been conducted as follows.

5 The signal processing and analysis strategies were assessed using simulated signals. Signals representing the simulated phase shift signals were generated in order to test the real-time processing arrangement for extracting the tissue transfer function based on Fast Fourier Transform (FFT). A particular interest exists in determining the absorption and reduced scattering coefficients of the tissue examined due to {HbO₂} and {Hb} and also due to the oxidised component of the respiratory enzyme
10 cytochrome aa₃. Therefore, for test purposes, three operating wavelengths were required in order to derive three equations that could be solved for the three unknown quantities. These were selected to be 760 nm, 840 nm 905 nm simply for the purpose of a test.

15 Two alternative implementations of the present invention have been tested.

In the first implementation, the extraction of the **scattering factor**, ζ , and the so-called **additive term**, Ψ , from equation 1 was used. Both of these, being related to scattering phenomena, appear as unknowns. For the purpose of this proof of principle embodied
20 with the present invention these parameters were determined by measuring the tissue transfer function at two modulating frequencies, ν_{m1} and ν_{m2} . The resulting set of two simultaneous equations was then solved to yield expressions for ζ and Ψ at each interrogating wavelength. These expressions were then used with equation 1 to determine values for the absorption coefficient, μ_a , and the reduced scattering
25 coefficient, μ_s' , of the tissue at each of the three wavelengths.

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In the second implementation, the use of the spatial variation of detected energy was employed. Signals simulating the modulation depth of the interrogating beam and the resulting attenuation seen in the detected beam were also fed into a digital signal processing module (DSP). The demodulation of the intensity modulated interrogating beam was then extracted successfully by an appropriate algorithm. This yielded values for a DC component and an AC component.

The extracted values of phase-shift, DC component and AC component simulated for three wavelengths and three transmit-receive distances were then used to derive values for the absorption coefficient, μ_a , and reduced scattering coefficient, μ_s' , of the tissue. A Diffusion approximation for photon propagation was used and both infinite and semi-infinite boundary conditions considered in order to evaluate various configurations of input point [11] and collection points [12_a, 12_b, 12_c].

As transmit-receive distance is varied so too do DC and AC components and phase shift. A derivation from the diffusion approximation allows these relationships to be considered to be linear with slopes S_{dc} , S_{ac} and S_{phase} . In order to extract the two unknowns, μ_a and μ_s' , any combination of two equations from the three linear relationships may be solved.

20

With either of the two possible methods tested for determining μ_a and μ_s' , the concentrations of the absorbing species of interest, that is to {HbO₂}, {Hb} and the oxidised component of the respiratory enzyme cytochrome aa₃, were then calculated from these using known values of absorber specific extinction coefficients at each of the three interrogating wavelengths.

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Practical measurements have been evaluated using certain modulated light sources could be used to generate the interrogating beam. It is feasible to use light emitting diodes LEDs (e.g. Hitachi type HLP 40RG) at three wavelengths,, 905 nm, 840 nm and 760 nm modulated at, for example, 48 MHz.. For extended penetration it is possible to use laser diodes e.g. Sony SLD104AU, modulated at, for example, 100 MHz. Peltier cooling of these devices is essential to achieve adequate overall signal to noise ratio.

The off-set frequency, chosen as an example to be 10 kHz., and the test phase-shifted signal were input to the DSP module where they were sampled. A conventional FFT algorithm was used to extract the phase information and this has shown successful recovery of the simulated phase-shift. Optical pathlength, which is equivalent to the product $d_p \zeta$, is calculated as $(\text{phase-shift})c/2\pi\nu_m$. Timing of analysis was programmed to test the possible use of up to four multiplexed intensity modulated light sources, emitting interrogating energy at wavelengths λ_1 , λ_2 , λ_3 and λ_4 selected from devices emitting at specific wavelengths between 700 nm and 1500 nm. DSP modules are available to enable, for example, 210 kHz sampling allowing more than four wavelengths to be used for determining the concentrations of more than four optically absorbing species.

20

In order to use the well-known heterodyne detection method the instrument has been tested with photomultipliers. Type R6357 may be used. Performance when modulated at the carrier plus offset, for example 100.001000 MHz, is adequate in terms of stability and linearity. Alternatively it is possible to use semiconductor detectors, for example PIN diodes, and mix the received signal with an offset reference signal to recover the phase shift and intensity information.

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The tests were carried out with optical phantoms having appropriate optical properties, of absorption and scattering. This can be produced from mixtures of milk and India ink.

5 Although the invention has been described with reference to laser sources, in particular laser diodes, it will be appreciated that the invention will operate with and includes within its scope other sources of electromagnetic radiation; one non-limiting example of such other sources is light-emitting diodes.

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CLAIMS:

1. A method of determining the concentration of a selected chemical or biological species *in vivo*, in which electromagnetic radiation is directed through the tissue and emergent radiation is analysed, the wavelength of the radiation being selected so as to correspond to a known absorption frequency for the species of interest and the radiation applied to the tissue being intensity modulated in accordance with a predetermined mathematical function, characterised in that:
- 5
- (i) emergent radiation is received by detectors positioned in at least three locations, each of which has a different linear separation from the radiation input;
- 10
- (ii) emergent radiation detected by said detectors is subjected to signal processing to determine, in real time, (a) the mean optical path lengths for each detector at each input wavelength; and (b) the attenuation of the input radiation at each detector and for each input wavelength; and
- 15
- (iii) the concentration of the species of interest in the tissue is calculated using known specific extinction coefficients for the species of interest at the wavelengths used and the mean optical path length and attenuation data derived from the input and emergent radiation by the signal processing step.
- 20
2. A method according to claim 1, characterised in that the mean optical path lengths for each detector at each input wavelength are obtained by determining the phase shifts between input and emergent radiation.
- 25
3. A method according to claim 2, characterised in that the phase shifts between input and emergent radiation for each detector and at each wavelength used are determined

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by a Fast Fourier Transform algorithm.

4. A method according to claim 1, 2 or 3, characterised in that the radiation input is at one or more wavelengths in the range from 700 and 1500 nm.

5

5. A method according to claim 4, characterised in that the radiation input is at one or more wavelengths in the range from 700 to 900 nm.

10

6. A method according to any preceding claim, characterised in that the radiation input consists of a time-multiplexed beam of two or more wavelengths.

7. A method according to claim 6, characterised in that said multiplexed beam is obtained by a time-sequenced switching (on and off) of a plurality of laser diodes the outputs of which are combined to form the multiplexed beam.

15

8. A method according to any preceding claim, characterised in that the input radiation is laser-generated light and in that its intensity is modulated by a function, f_m , by means of a modulating circuit.

20

9. A method according to claim 8, characterised in that two or more modulating frequencies are used.

10. A method according to claim 9, characterised in that said modulating frequencies

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are in the range 50 MHz to 500 MHz.

11. A method according to any preceding claim, characterised in that emergent radiation is collected and is transported by individual optical fibres to a photomultiplier where it is detected and amplified.

5

12. A method according to claim 11, characterised in that the photomultiplier is used in the heterodyne mode.

13. A method according to claim 12, characterised in that one dynode is fed with a signal shifted by 10kHz to 15kHz from the modulating frequency applied to the input radiation.

10

14. A method according to any preceding claim, characterised in that (i) the species of interest are {Hb}, {HbO₂} and the oxidised component of the respiratory enzyme cytochrome aa₃; and (ii) the wavelengths of the input radiation are 760 nm, 840 nm and 905 nm.

15

15. Apparatus for use in determining the concentration of a selected chemical or biological species *in vivo*, which comprises:

20

(a) a plurality of electromagnetic radiation sources;

(b) a modulation circuit arranged to modulate the outputs of said radiation sources at two or more modulation frequencies;

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(c) a frequency selection circuit arranged select said modulation frequencies;

(d) means for inputting the modulated electromagnetic radiation into human or animal tissue which is to be examined;

5 (e) at least three detectors for attachment to said human or animal to receive radiation emergent from said tissue; and

(f) signal processing means for processing data derived from said detectors, said modulation circuit and said frequency selection circuit.

10 16. Apparatus as claimed in claim 15, characterised in that said electromagnetic radiation sources are laser diodes.

17. Apparatus as claimed in claim 15, characterised in that said electromagnetic radiation sources are light-emitting diodes.

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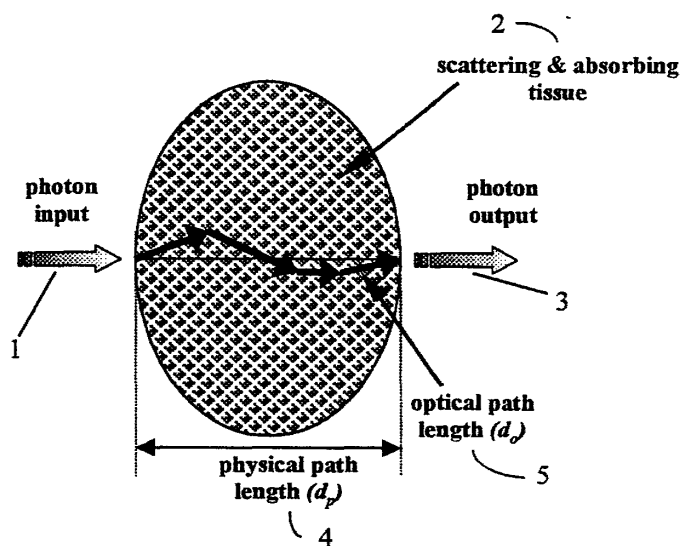


Fig 1

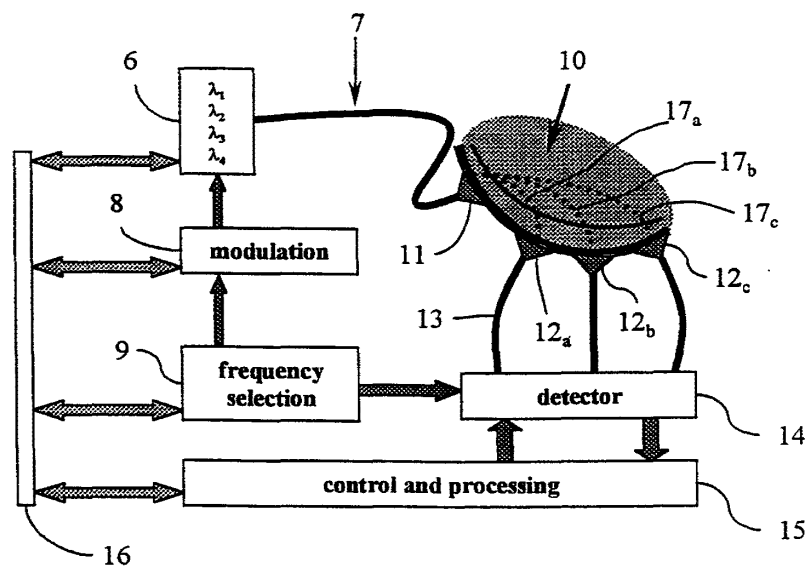


Fig 2

P Rolfe Optical
Monitoring

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 G01N21/49		International Application No PCT/GB 99/03563
According to International Patent Classification (IPC) or to both national classification and IPC -		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 G01N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 710 832 A (HAMAMATSU) 8 May 1996 (1996-05-08) abstract page 7, line 25 - line 35 page 9, last paragraph page 10, line 7 - line 27 page 10, line 40 - line 48 page 11, line 5 - line 17 page 11, line 22 - line 28 page 15, line 13 - line 17 claim 9; figure 7	1,4-6,8, 9,11
A	--- -/--	15,17
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search 16 February 2000		Date of mailing of the international search report 23/02/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016		Authorized officer Thomas, R.M.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/03563

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 803 909 A (MAKI) 8 September 1998 (1998-09-08) column 1, paragraph 1 - paragraph 2 column 8, line 1 - line 30 column 10, line 43 - column 11, line 51	15-17
A	column 19, line 33 - line 58 column 20, line 26 - line 30 column 22, line 6 - line 11 column 22, line 21 - line 28 column 22, line 34 - line 46	14
Y	figures 2, 18, 20	1-9, 11
Y	US 5 752 519 A (BENARON) 19 May 1998 (1998-05-19) column 9, line 48 - column 10, line 54 column 17, line 1 - line 5 column 17, line 12 - line 19 figures 6, 7	1-9, 11
A	US 5 692 504 A (ESSENPREIS) 2 December 1997 (1997-12-02) column 10, line 26 - column 11, line 14 column 15, line 8 - line 9 column 16, line 21 - line 34 column 16, last paragraph figure 11	1, 8-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. .onal Application No

PCT/GB 99/03563

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0710832 A	08-05-1996	JP 8136448 A	31-05-1996
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		EP 0760091 A	05-03-1997
		JP 10500338 T	13-01-1998

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

To:

KNOBBE, MARTENS, OLSON
Attn: Altman, Daniel E.
AND BEAR, LLP
2040 Main Street, Fourteenth Floor
Irvine, CA 92614
ETATS-UNIS D'AMERIQUE

(PCT Rule 44.1)

Date of mailing
(day/month/year)

02/10/2009

Applicant's or agent's file reference

MLHUM.002VPC

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2009/052756

International filing date
(day/month/year)

04/08/2009

Applicant

MASIMO LABORATORIES, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Louis Kainde

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1b(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43b.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference MLHUM.002VPC	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2009/052756	International filing date (day/month/year) 04/08/2009	(Earliest) Priority Date (day/month/year) 04/08/2008
Applicant MASIMO LABORATORIES, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 2b
☒ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☐ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2007)

CX-1622

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2009/052756

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/25112 A (ROLFE PETER [GB]) 4 May 2000 (2000-05-04) abstract page 7, line 16 - page 8, line 17 page 13, lines 1-4	1-3
X	US 6 816 241 B2 (GRUBISIC DRAGAN [US]) GRUBISIC DRAGAN [US] ET AL) 9 November 2004 (2004-11-09) abstract column 1, lines 10-15, 32-38 column 3, line 66 - column 4, line 34 column 5, line 2 - column 6, line 9 column 7, lines 48-65 column 8, line 60 - column 10, line 7	1-6, 18-33
Y	----- -/--	8-17

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

24 September 2009

Date of mailing of the international search report

02/10/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Ferrigno, Antonio

Form PCT/ISA/210 (second sheet) (April 2005)

CX-1622

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/052756

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/211924 A1 (DALKE DAVID [US] ET AL) 21 September 2006 (2006-09-21) cited in the application abstract paragraphs [0006] - [0009] paragraphs [0061] - [0066], [0068] paragraphs [0070], [0075] paragraphs [0091] - [0096], [0107] claims 1,15	1-3,5,7, 18,25, 34-36
Y	-----	8-14
X	US 6 172 743 B1 (KLEY VIC [US] ET AL) 9 January 2001 (2001-01-09) abstract column 7, lines 30-64 column 8, line 50 - column 9, line 7 -----	1,2,18, 25
X	US 5 676 143 A (SIMONSEN JAN HENNING [DK] ET AL) 14 October 1997 (1997-10-14) the whole document -----	1,2
Y	US 2004/049237 A1 (LARSON DENNIS E [US] ET AL) 11 March 2004 (2004-03-11) paragraph [0042] -----	15-17

3

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

CX-1622

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/052756

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0025112	A	04-05-2000	EP 1125109 A1	22-08-2001
US 6816241	B2	09-11-2004	AU 9625901 A	08-04-2002
			WO 0226123 A1	04-04-2002
			US 2002041166 A1	11-04-2002
US 2006211924	A1	21-09-2006	EP 1860989 A1	05-12-2007
			EP 1860990 A1	05-12-2007
			EP 1860991 A1	05-12-2007
			EP 1860992 A1	05-12-2007
			EP 1863380 A2	12-12-2007
			EP 1860993 A1	05-12-2007
			EP 1860994 A1	05-12-2007
			EP 1860995 A1	05-12-2007
			EP 1860996 A1	05-12-2007
			EP 1895892 A1	12-03-2008
			EP 1860997 A1	05-12-2007
			JP 2008531211 T	14-08-2008
			JP 2008531212 T	14-08-2008
			JP 2008535540 T	04-09-2008
			JP 2008531214 T	14-08-2008
			JP 2008531215 T	14-08-2008
			JP 2008532589 T	21-08-2008
			JP 2008538186 T	16-10-2008
			JP 2008531216 T	14-08-2008
			JP 2008531217 T	14-08-2008
			JP 2008531218 T	14-08-2008
			JP 2008531225 T	14-08-2008
			US 2008220633 A1	11-09-2008
			US 2006220881 A1	05-10-2006
			US 2006211922 A1	21-09-2006
			US 2006241358 A1	26-10-2006
			US 2006229509 A1	12-10-2006
			US 2006211923 A1	21-09-2006
			US 2006241363 A1	26-10-2006
			US 2006238358 A1	26-10-2006
			US 2006226992 A1	12-10-2006
			US 2006211925 A1	21-09-2006
			US 2006211932 A1	21-09-2006
			WO 2006094107 A1	08-09-2006
			WO 2006094108 A1	08-09-2006
			WO 2006094109 A1	08-09-2006
			WO 2006094155 A1	08-09-2006
			WO 2006115580 A2	02-11-2006
			WO 2006094168 A1	08-09-2006
			WO 2006094169 A1	08-09-2006
			WO 2006094170 A1	08-09-2006
			WO 2006094171 A1	08-09-2006
			WO 2006118654 A1	09-11-2006
			WO 2006094279 A1	08-09-2006
US 6172743	B1	09-01-2001	NONE	
US 5676143	A	14-10-1997	NONE	
US 2004049237	A1	11-03-2004	AU 2003249174 A1	02-02-2004
			EP 1521616 A2	13-04-2005
			JP 2005532870 T	04-11-2005

Form PCT/ISA/210 (patent family annex) (April 2005)

CX-1622

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/052756

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004049237 A1		WO 2004007019 A2	22-01-2004

Form PCT/ISA/210 (patent family annex) (April 2005)

PATENT COOPERATION TREATYFrom the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)**Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/US2009/052756International filing date (day/month/year)
04.08.2009Priority date (day/month/year)
04.08.2008International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00Applicant
MASIMO LABORATORIES, INC.**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040
Fax: +31 70 340 - 3016

Date of completion of
this opinionsee form
PCT/ISA/210

Authorized Officer

Ferrigno, Antonio

Telephone No. +31 70 340-2174



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2009/052756

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2009/052756

**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	<u>8-17, 19-24, 28-30</u>
	No: Claims	<u>1-7, 18, 25-27, 31-36</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-36</u>
Industrial applicability (IA)	Yes: Claims	<u>1-36</u>
	No: Claims	

2. Citations and explanationssee separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/052756

Re Item V.

1 Reference is made to the following documents:

- D1 : WO 00/25112 A (ROLFE PETER [GB]) 4 May 2000 (2000-05-04)
- D2 : US 6816241 B2 (GRUBISIC DRAGAN [US] GRUBISIC DRAGAN [US] ET AL) 09 November 2004 (2004-11-09)
- D3 : US 2006/211924 A1 (DALKE DAVID [US] ET AL) 21 September 2006 (2006-09-21) cited in the application
- D4 : US 6 172 743 B1 (KLEY VIC [US] ET AL) 9 January 2001 (2001-01-09)
- D5 : US 5 676 143 A (SIMONSEN JAN HENNING [DK] ET AL) 14 October 1997 (1997-10-14)
- D6 : US 2004/049237 A1 (LARSON DENNIS E [US] ET AL) 11 March 2004 (2004-03-11)

US 4 258 719 A (LEWYN LANNY L) 31 March 1981 (1981-03-31)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 discloses (the references in parentheses applying to this document):

A method of measuring an analyte (cf. abstract) based on multiple streams of optical radiation measured from a measurement site (cf. figure 2), said method comprising:
emitting a sequence of optical radiation pulses to the measurement site (cf. abstract, page 7, lines 16-23) ;
detecting at a first location (12a) a first stream of optical radiation from the measurement site;
detecting at least at one additional location (12b) different from the first location an additional stream of optical radiation from the measurement site; and
determining an output measurement value indicative of the analyte based on the

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/052756

detected streams of optical radiation (cf. abstract, page 8, lines 4-6) figure 2).

Hence, the subject-matter of claim 1 is disclosed in document D1.

- 2.2 Bearing in mind that an array of detectors allows detecting at a plurality of locations streams of optical radiation (cf. D1, page 8, lines 14-17), the subject-matter of claim 1 is disclosed also in documents D2-D5 (cf. the corresponding passages cited in the search report).

3 INDEPENDENT CLAIM 7

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 7 is not new in the sense of Article 33(2) PCT. Document D3 discloses (the references in parentheses applying to this document):

A front-end interface (4030) for a noninvasive, physiological sensor, said front-end interface comprising:

a set of inputs configured to receive signals (2500, cf. figures 7 and 40) from a plurality of detectors (cf. figures 2400, cf. paragraph 58, figures 25,26,40) in the sensor;

a set of transimpedance amplifiers (implicit: cf. paragraphs 72, 107) configured to convert the signals from the plurality of detectors into an output signal having a stream for each of the plurality of detectors; and

an output configured to provide the output signal (cf. figure 40).

4 INDEPENDENT CLAIM 15

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 15 does not involve an inventive step in the sense of Article 33(3)PCT.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2009/052756

- 4.1.1 Document D2, discloses (cf. passages cited in the search report) a device from which the subject-matter of independent claim 15 differs in that:

the digital conversion is carried out by switched-capacitor circuits.

- 4.1.3 In document D2 no details are given about the circuits for A/D conversion. The problem to be solved by the present invention may therefore be regarded as to provide a specific embodiment of such circuits.

- 4.1.4 D6 discloses (cf. paragraph 42) switched-capacitor circuits for A/D conversion. The skilled person would therefore regard it as a normal option to include this feature in the device described in document D2, in order to solve the problem posed. The subject-matter of claim 15 thus cannot be considered inventive (Article 33(3) PCT).

5 INDEPENDENT CLAIM 18

- 5.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 18 is not new in the sense of Article 33(2) PCT. The subject-matter of claim 18 is just directed to the essential features of a processor unit having inputs signals from a detector array, said signals being converted in digital form and then processed by a signal processor. These essential features are disclosed in all documents D2-D4 (cf. the corresponding passages cited in the search report).

6 INDEPENDENT CLAIM 25

- 6.1 The same reasoning applies, mutatis mutandis, to the subject-matter of independent claim 25, which is just directed to the essential features of a multi-stream emitter and which is disclosed in all documents D2-D4 (cf. the corresponding passages cited in the search report), which therefore is therefore also considered not new (Articles 33(1) and 33(2) PCT).

7 DEPENDENT CLAIMS 2-6, 8-14, 16, 17, 19-24, 26-36

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference MLHUM.002VPC	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2009/052756	International filing date (<i>day/month/year</i>) 04 August 2009 (04.08.2009)	Priority date (<i>day/month/year</i>) 04 August 2008 (04.08.2008)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MASIMO LABORATORIES, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:



Box No. I

Basis of the report



Box No. II

Priority



Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability



Box No. IV

Lack of unity of invention



Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement



Box No. VI

Certain documents cited



Box No. VII

Certain defects in the international application



Box No. VIII

Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

	Date of issuance of this report 08 February 2011 (08.02.2011)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Masashi Honda e-mail: pt08.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)Applicant's or agent's file reference
see form PCT/ISA/220**FOR FURTHER ACTION**
See paragraph 2 belowInternational application No.
PCT/US2009/052756International filing date (day/month/year)
04.08.2009Priority date (day/month/year)
04.08.2008International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00Applicant
MASIMO LABORATORIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinionsee form
PCT/ISA/210

Authorized Officer

Ferrigno, Antonio

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/US2009/052756**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1 (a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments: